

**AUTOLUMO A1800 AUTOLUMO A1820**

**AUTOLUMO A1860 AUTOLUMO A1880**

Automatic Luminescence Immunoassay Analyzer  
**Operating Manual**

2022-06-09

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This document can not be considered as substitute of official training of Autobio. Automatic Luminescence Immunoassay Analyzer shall only be operated by personnel who has been authorized and trained by Autobio.

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## CONTACT

In the event of any questions or doubts related to using the Automatic Luminescence Immunoassay Analyzer, please send an email with a short description of the question to the address below or contact the post-sales service. Any suggestions for improvements to products and services are gladly acceptable.



Autobio Labtec Instruments Co., Ltd.  
No.199,15th Ave, National Eco & Tech Zone, Zhengzhou 450016,  
China

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Website	<a href="http://www.autobio.com.cn">www.autobio.com.cn</a>
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## EC Representative



OBELIS S.A  
Bd.Général Wahis, 53  
1030 Brussels,  
Belgium

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## In Vitro Diagnostic Medical Device



This product is used for In Vitro Diagnostic purpose.

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## Waste Electrical and Electronic Equipment (WEEE)



In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), the presence of the left symbol on the product or on its packaging indicates that this item must not be disposed of in the way that normal unsorted municipal waste stream is mixed with other normal household-type waste. Instead, the responsibility should be taken by users to dispose of this element by returning it back to a collection area dedicated for recycling the waste of electrical and electronic equipment. The waste, which may be harmful to physical and potentially mental health or makes it impossible to keep a favorable environment, must be collected separately, observing the relevant legal regulations effective, which makes for recycling and minimizing the bad effect on human physical health and the environment. In order to acquire more information with respect to the correct disposal of this product, please contact your local authority or the dealer who supplied this product.

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The manual is mainly used for giving instructions to users for instrument related operation and general maintenance, which includes the following: general description, safety features, description and quality control of function and operation, measures taken in case of emergency, product labelling and maintenance, etc.,

# 1 General Description

## 1.1 Safety Information

### 1.1.1 Safety Features

Safety labels are affixed on the instrument to remind the user of safety. Please read the label and the operating manual carefully prior to operating the instrument. If any questions, please contact Autobio.

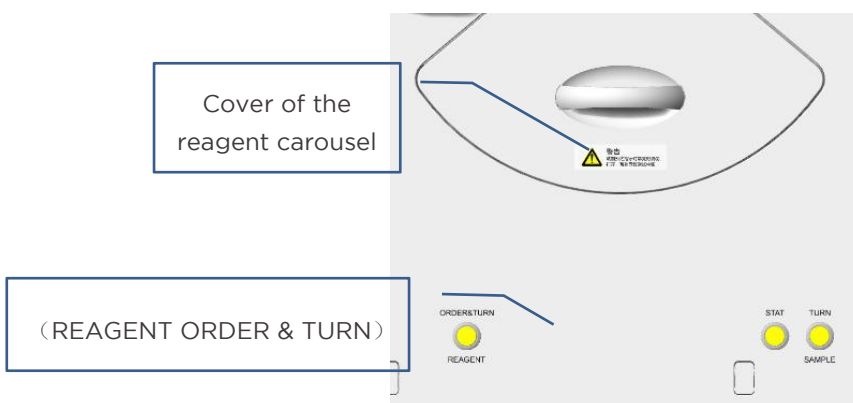
Prior to usage, user must be trained by Autobio to avoid risks caused by incorrect action.

### 1.1.2 Protective Device/Safety Equipment

The instrument is designed according to relevant standards requirements and it has protective device.

#### 1.1.2.1 Stop Protective Function of Reagent Carousel Cover

There are three status: reagent carousel cover/turn button/indicator ( REAGENT ORDER & TURN ) : ON, FLASH, OFF(See table below):



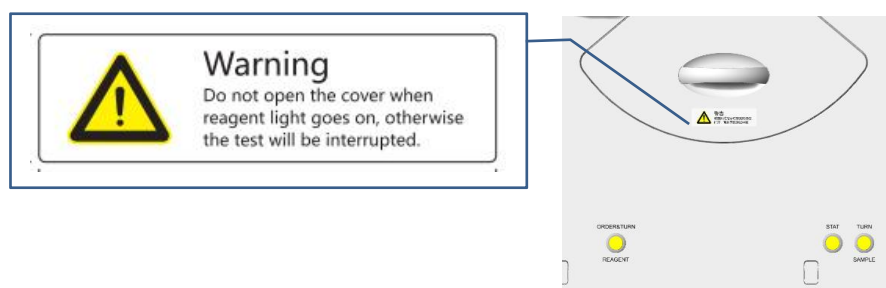
**Indicator flash:**It turns to light ON after flash: indicating the user system has received the order (button reaction), and it is prohibited to open the reagent carousel cover to change the reagent kit under this status.

**Continuously flash:** Indicating that the instrument prompts the user to replace the kit. In this state, the reagent carousel cover can be opened to replace the kit.

**Indicator on:** Indicating reagent management unit is under work status, and do not open the reagent carousel cover.

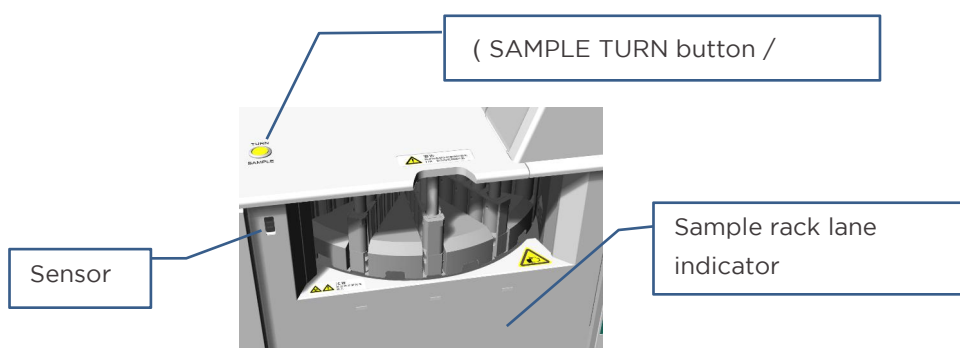
**Indicator off:** Indicating the reagent management unit can not work.

If the REAGENT carousel cover is opened while the REAGENT ORDER/TURN button/reagent ORDER/TURN is on, the system will stop the reagent carousel spinning and stop all reagents in process to prevent damage and to prevent reagent adding improperly and probes crashing during testing. Please pay attention to the label on the instrument (as shown below), which is a standard operation! After the operation is complete, close the carousel cover. Otherwise, subsequent tests will be affected.



### 1.1.2.2 Protective Function of the Central Door Open-system

The sensor of central door has the function of checking whether door is opened.



**Three status of indicator:** green, orange, off (shown as figure above)

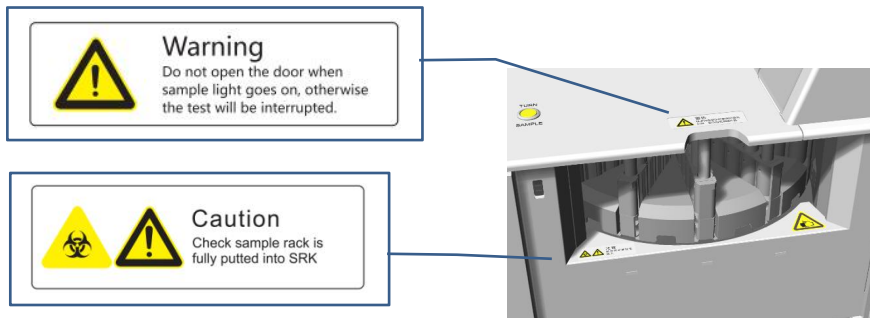
**Indicator is green:** Indicating the sample racks have completed the test and can be taken off or replaced.

**Indicator is orange:** Indicating the sample racks have been in queue and can not be taken

off or replaced.

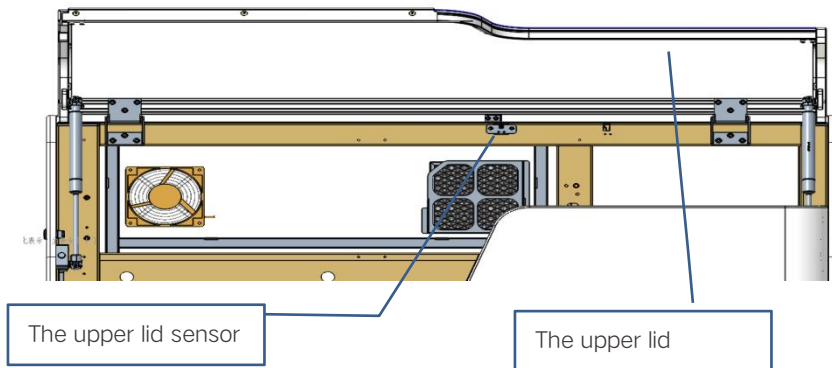
**Indicator is off:** When it is ready, button can be turned and the sample can be put in or taken out.

If the central door is opened during the test, the system will not perform sampling activities until the central door is closed in order to prevent harm to the user and damage to the instrument. Please pay attention to the label on the instrument (as shown below), and please operate according to the specification! After the operation is complete, close the central door in time; Otherwise, subsequent tests will be affected.



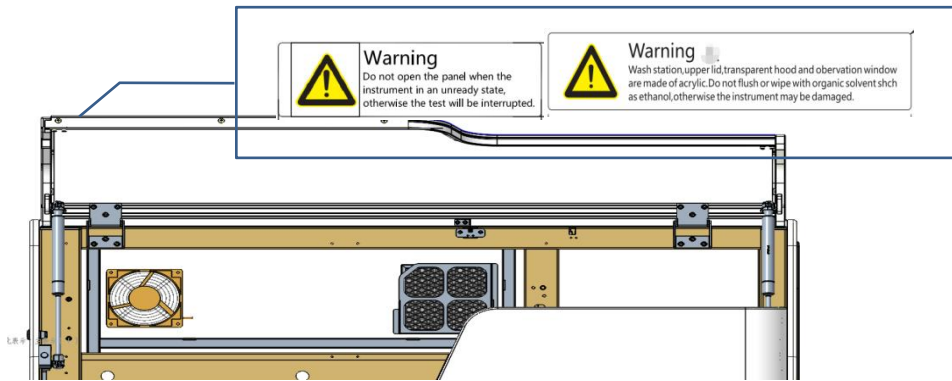
### 1.1.2.3 Protective Function of the Upper Lid Open-system

The sensor has the function of checking whether the upper lid is open or not (show as below).







When the instrument is ready or unready(not under testing), the upper lid can be opened to check and change the consumables(system wash and dilution).










When the instrument is under testing, the system will stop when opening the upper lid to prevent the personnel from being hurt. Please read the label on the instrument (as shown below) and operate it according to the specification.




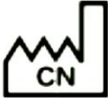



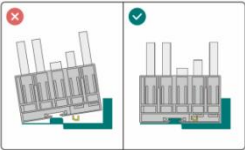
### 1.1.3 Safety Symbols and Others

This manual employs the following symbols and signal words to indicate hazards or instructions. The safety instructions are always placed before an action.

Symbol	Description
	Biological Risks.
	Caution! Possibility of Electric Shock! Potential risk of electric shock, especially for the high voltage parts, such as photomultiplier tube (PMT), and power module. It's too dangerous to open these parts for checking and maintenance if operator is not trained professionally.
	General warning sign! The operating manual must be consulted in all cases where the symbol is marked, in order to find out the nature of the potential hazards and any actions which have to be taken to avoid them.
	Warning; Crushing of Hands! Watch your hand when opening or closing the cover of the instrument.

	<p>Warning; Sharp Element!</p> <p>The sharp element may hurt operator. When operating instruments, don't put your hand or any body parts in these areas.</p>
	<p>Alternating Current.</p>
	<p>Protective Conductor Terminal.</p>
	<p>“OFF”(Power).</p>
	<p>“ON”(Power).</p>
	<p>Disposal of Electrical and Electronic Equipment:</p> <p>The equipment must not be processed according to the conventional waste disposal. It is the responsibility of the user to return it to the waste collection point of the electrical and electronic equipment for recycling.</p>
	<p>In Vitro Diagnostic Medical Device.</p>
	<p>Consult Instructions for Use or Consult Electronic Instructions for Use</p>
	<p>Manufacturer.</p>



	<p>Authorized Representative in the European Conformity / European Union.</p>
	<p>European Economic Area Conformity.</p>
	<p>Date and Country of Manufacture.</p>
	<p>Catalogue/Reference Number.</p>
	<p>Serial Number.</p>
	<p>Model Number.</p>
	<p>Unique Device Identifier.</p>
	<p>Temperature Limitation.</p>
	<p>Humidity Limitation.</p>
	<p>The sample racks should be inserted against the bottom according to the right picture.</p> <p>The sample rack can not be inserted according to the left picture which shows a wrong indication.</p>

**CAUTION:**

Failure to observe the content of symbols or operating manual, including the warnings, precautions and prompts, and using the damaged or missing safety symbols, will cause system damage or adverse impacts on system functionality; or may result in physical injury or deterioration in the state of health, damage to property or material!

### 1.1.4 General Safety

The operating manual gives important instructions for handling the system. Safety instructions must be observed at all times. Before or during the process of operation, the following items must be observed:

**CAUTION:**

- 1) Do not perform any operations which are not described in the manual. If trouble occurs, please call post-sales service.
- 2) The operating manual must be accessible to the user at any time.
- 3) As for maintenance and service, it is forbidden to modify the Automatic Luminescence Immunoassay Analyzer and replace the components or accessories of the instrument.
- 4) It is not allowed to use parts which are not provided by Autobio. It is not permitted to remove protective device.
- 5) Non-manufacturer personnel can not install or maintain the Automatic Luminescence Immunoassay Analyzer, nor make any changes during installation.

**NOTE:**

Improper connection between Automatic Luminescence Immunoassay Analyzer and the peripheral devices with mains supply, as well as usage of damaged cables may result in severe personal injury even lethal consequences and property damage (e.g.fire).

#### 1.1.4.1 Liability

It is the users' responsibility to comply with national and local law's regulations and laboratory procedures for installation and operation of the instrument. The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically.

Autobio is not liable for any loss or damage including consequential or special damages resulting from the misuse of the contained information or other fault of personnel and contractors. Additionally, the manufacturer assumes no liability for any damages, including those to the third parties, which is caused by improper use or handling of the system.

The instrument may only be used in accordance with its intended use. Only use the consumables and accessories described in the manual.

### 1.1.4.2 Technical Condition

Automatic Luminescence Immunoassay Analyzer corresponds in its design and construction to the current state of the art technology. Unauthorized modifications or changes, especially such that affect the safety of the staff and the environment, are generally not allowed.



#### CAUTION:

- 1) Any manipulation of the safety device is prohibited! In case of an accident manipulations of the safety equipment, it will be interpreted as deliberate!
- 2) The operator must only operate the device in a sound and operationally safe condition. The technical condition must always comply with the legal requirements and regulation.
- 3) Prior to every usage, the device must be checked to ensure its sound condition.
- 4) Any changes in the device affecting its safety must be reported to Autobio by the the operator.

### 1.1.4.3 Requirements for the Operating Personnel

Automatic Luminescence Immunoassay Analyzer must only be used by professional laboratory personnel taking into consideration the operating manual and the instruction for use of corresponding IVD kits.

Apart from the information in the operating manual and instruction for use of the corresponding IVD kits, the regulatory requirements of the applicable country of use must be observed and complied with. The operator must ascertain the latest version of these regulations.



#### CAUTION:

- 1) The device must only be commissioned, operated and serviced by manufacturer or agent authorized by Autobio.
- 2) The operation or servicing of the device by minors or individuals under the influence of alcohol, drugs or medication is not permitted.
- 3) It must be ensured that only authorized personnel works at the device. The operator must be familiar with the dangers arising from samples and excipients. Suitable personnel protection equipment must be worn.
- 4) Any changes in the device affecting its safety must be reported to Autobio by the the

operator. Prior to pauses or at the end of the work, appropriate skin cleaning and protection measures must be carried out.

5) Eating, drinking and smoking at the location of the device are prohibited!

### **1.1.5 Biological Risks**

When operating the device or handling related liquid, such as reagent, human serum, blood products, etc., user may be exposed to potentially infectious materials. Please strictly comply with Good Laboratory Practice when dealing with biological hazards or repairing and maintaining the Device:

Please take appropriate protective measures, such as wearing disposable gloves, waterproof lab coats and safety goggles.

Observe national and local laboratory standards and regulations. It is forbidden using damaged or aged hoses containing solution. Please replace them through contacting with Autobio or local agent.

Materials used in the assays must be considered potentially infectious agents. They should therefore be decontaminated and disposed of in accordance with standard and regulations of laboratory specified by local government.

The following articles should be disposed as potential biohazard:

- a) All in-vitro diagnostic instruments, pre-treated kit, patient sample, calibrators based on serum, QC materials and medical wastes.
- b) Articles coming into contact with the potential biohazard, such as pipettor tip, sample tube or cup, reaction vessel, waste container, washing tank, etc.,
- c) When hoses and parts containing liquid become aged or damaged, please stop using them immediately and contact with after sale service or local distributor to change them.

#### **NOTE:**

- 1) Inclusions in the solid waste container may be potentially biological risks, and it may be infectious upon contact.
- 2) Please dispose the solid wastes in accordance with relevant procedure and applicable local regulation, and wear the appropriate personal protective equipment (PPE).
- 3) Please contact Autobio if the instrument needs to be scrapped, and it can not be disposed as a regular article.

### **1.1.6 Electrical Hazards**

The system of Automatic Luminescence Immunoassay Analyzer does not pose uncommon electrical hazards to operators if it is installed and operated without alteration and is connected to a power source that meets required specifications. It is essential to the safe

operation of any system to have basic electrical hazard awareness. Life threatening electrical voltages may occur in the interior of the Automatic Luminescence Immunoassay Analyzer, and please strictly observe the elements of electrical safety, which include but are not limited to the following:

**CAUTION:**

Any work on the interior of the device may only be carried out by manufacturer or agent authorized by Autobio.

- 1) Keep liquids away from all connectors of electrical or communication components.
- 2) Do not touch any switches with wet hands.
- 3) Do not replace the removable mains cable of the device by a mains cable that does not meet the specifications (without protective ground conductor).
- 4) Any defects, such as loose connections, faulty or damaged cable, must be repaired without delay.
- 5) Do not put connecting cables at accessible place in order to avoid squeeze or damage.
- 6) Do not interrupt any electrical connection or service any electrical or internal components while the power is on.

**NOTE:**

Use an independent supply source to prevent device malfunction at site. It is strictly prohibited to add any other device to the socket of Automatic Luminescence Immunoassay Analyzer (if available) without permission of Autobio.

**NOTE**

Severe personal injury or extensive damage to the device may occur. It will not trigger severe personal injury with lethal consequences and property damages unless not observing the rules and regulations for the safe electrical operation.

### 1.1.7 Physical Hazards

For most automated device, there is potential physical injury or bodily harm from moving mechanical components whenever the system is running because of following hazards: radiation (laser light, etc.), heavy objects, trip hazards, moving parts of the instrument and sharp units, etc.,

Commissioning or installing the instrument must comply with the operating manual. Basic safety elements include but are not limited to the following (If applicable):

- 1) Do not touch directly with the sharp metal edges.
- 2) Do not overlook or ignore a safety equipment.
- 3) Keep all protective covers and barriers at right place.

- 4) Body part is not allowed to enter into the mechanical movement arrange.
- 5) Do not contact with the probes that are contaminated with potentially infectious material.
- 6) Do not look into the laser beam.
- 7) Wear off watches and reflective jewelry before operating the laser module.

**NOTE:**

Do not wear clothing or ornaments that could have an interference with the system.

### **1.1.8 Fluids Hazards**

Users may be exposed to hazardous chemicals or agents when handling , loading or removing the reagent kits, and disposing the liquid waste. Observing the instructions below can minimize the risks of fluids hazard.

- 1) Cleaning or decontamination shall not cause a direct hazard, such as an electrical hazard or a hazard arising from corrosion or weakening of structural parts.
- 2) Absorb the spill with absorbent material.
- 3) Observe the manual of IVD reagent kits.
- 4) Wear appropriate protective equipment, such as impervious gloves, protective goggles and clothing to protect eyes and skins from contacting with hazardous fluids.
- 5) Before handling IVD reagents, consult corresponding product-specific MSDS (Material Safety Data Sheets) for safe use instructions and precautions.
- 6) Seek medical attention if irritation or signs of toxicity occur after exposure.
- 7) If liquid spills onto the surface of the instrument, clean it up immediately. If liquid spills onto the inside of the instrument, contact the manufacturer or agent.

### **1.1.9 Electromagnetic Wave Interference**

Automatic Luminescence Immunoassay Analyzer fulfills the corresponding requirements for transient emissions and interference resistance from IEC 61326 series. Only cables provided by Autobio can be used to minimize electromagnetic wave interference. Please read the following content carefully and ensure the ambient environment is appropriate:

- 1) Automatic Luminescence Immunoassay Analyzer is designed and tested according to CISPR Class A. Under some circumstances, it may cause radio interference, please take protective measures.
- 2) It is recommended that the electromagnetic environment should be evaluated before operation.

3) Do not operate the instrument near sources of strong electromagnetic radiation (such as unshielded, deliberately operated high frequency sources), as this may affect proper operation of the device.

4) Check the power supply cable periodically to avert it becoming loose.

**NOTE:**

1) Autobio is responsible for providing electromagnetic compatibility information of Automatic Luminescence Immunoassay Analyzer.

2) User is responsible for maintaining the electromagnetic compatibility environment where Automatic Luminescence Immunoassay Analyzer can work properly as intended use.

### **1.1.10 Other Residual Hazards**

Notwithstanding the manufacturer has try as possible as they can to reduce the risks to an acceptable level, such as inherent safe design and protective measures, users may be still at an unfavourable situation.

In regards of risk management, the system has been designed and manufactured based upon the standard ISO 14971.

The materials and components of the Automatic Luminescence Immunoassay Analyzer is made and the reagents used on the instrument do not endanger the safety or health of users. Autobio has applied many principles for reducing risks, which include but are not limited to the following:

- 1) Eliminate or reduce risks as far as possible (an inherently safe design and construction);
- 2) Take the necessary protective measures related to the risks that cannot be eliminated, which can refer to the 1.1.5-1.1.9;
- 3) Inform users of the residual risks due to any defects of the protective measures adopted, indicate any particular training required, and provide operator with information of protective device/safety equipment;
- 4) Estimate the risks of hazardous situations, taking into account the severity of potential harm and the possibility of its occurrence by the application of an appropriate FMEA (Failure Mode Effect Analysis) methodology;

**NOTE:**

Autobio assumes no responsibilities concerning the losses or damages arising from the improper operations or maintenance by unauthorized personnel. It is recommended that users contact the manufacturer or agent immediately in case emergency occurs.

### 1.1.11 Ergonomic

Based on the ergonomic principles, the Automatic Luminescence Immunoassay Analyzer is designed regarding to the user habits, interface layout, information prompts and software interface operation safety etc., to reduce discomforts fatigue, physical and psychological stress. If the user needs other functions, please contact customer service of Autobio.

The documents and materials related to safety operation are included in the accessory case, e.g. the operating manual, waste liquid container, reaction vessels, and fuse etc.,.

## 1.2 Reporting Instrument Anomalies

Users are encouraged by Autobio to report any anomalies observed in the performance, appearance, labelling or packaging of instrument. Autobio or its local representatives will carry out a thorough analysis of possible defects, and encourages users to report the anomalies in sufficient detail, e.g. serial number, UDI, product model or catalogue/reference number, along with a description of the relevant observations and supported with photographic or other descriptive material if available. It is advisable that products with suspected defects be quarantined and processed according to the advice of Autobio authorized representatives or local agent. Please preserve the whole product, together with the packaging material for further analysis.

## 1.3 Vigilance Information

If the unlikely case of a suspected hazardous situation caused or affected by the use the instrument of Autobio occurred, please contact Autobio or its local representatives directly and without delay, which can refer to the important contact information of chapter 1.4. Additionally, local competent authorities have standard reporting forms available for reporting possible adverse effects of IVD medical devices, and users should follow any local regulations or guidance provided by the local authorities.

## 1.4 Product and Manufacturer Information

### Product Information:

Product Name: Automatic Luminescence Immunoassay Analyzer

Product Model: AutoLumo A1800, AutoLumo1820, AutoLumo A1860, AutoLumo1880

Manufacturing Date: Refer to the nameplate label of the instrument.

Lifetime: 10 Years

Applicable Software Version: V1.0

### NOTE:

The lifetime of the instrument is closely related to the operating environment and



frequency of use. Regular maintenance can duly extend the lifetime. If there is any problem or alarming prompt, please call customer service or access the website of <https://www.autobio.com.cn/>.

If the components mounted on the analyzer were to be changed, the only way to purchase would be from Autobio other than other manufacturers. Do not open the cover of the analyzer during running, or it will abort the assay.

**Manufacturer:**

Name: Autobio Labtec Instruments Co., Ltd.

Legal Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China

Tel: [86]-371-6798-5313

**Post-sales Customer Service:**

Name: Autobio Diagnostics Co., Ltd.

Legal Address: No.199, 15th Ave, National Eco & Tech Zone, Zhengzhou 450016, China

Tel: [86]-371-6798-5313

**NOTE:**

Please prepare the serial number of the instrument before contacting post-sales service.

## 1.5 Manual Version Information

**Manual version:** V1.1

**Issuance time:** 2022-05-19

Changes to the previous version are in the following:

- 1)The symbols of UDI, model and country of manufacture were added in the section1.1.3;
- 2)The words of “Consult Instructions for Use” were changed to “Consult Instructions for Use or Consult Electronic Instructions for Use”.

Every effort has been made by Autobio to ensure that the information provided in this manual is accurate as of the date of publication. Updates or modifications can be occasionally made, in which case the publication date and the version number will be changed. To make sure you are using the latest version of the operating manual, please keep a close contact with your local representative.

## 2 Product Description

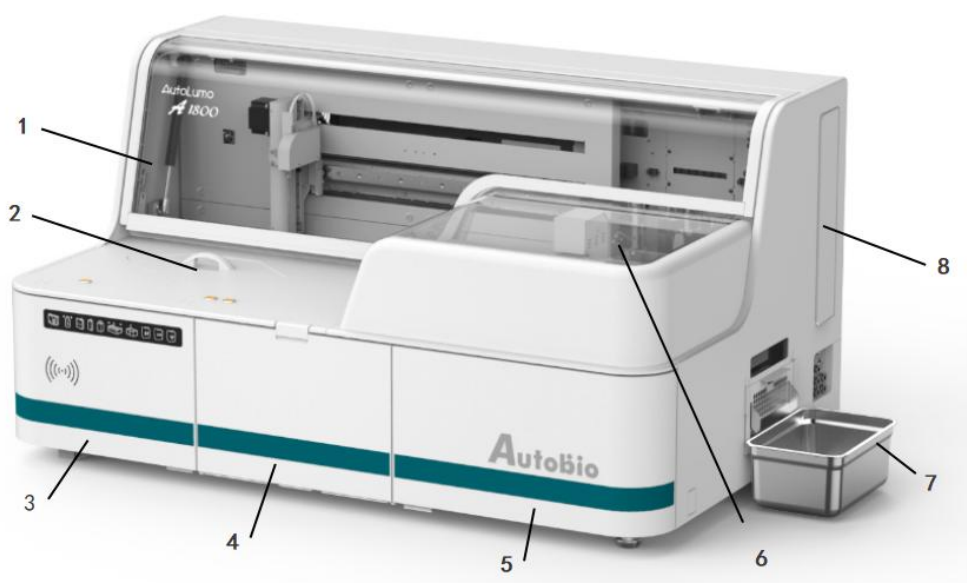
Automatic Luminescence Immunoassay Analyzer has four models: AutoLumo A1800, AutoLumo1820, AutoLumo A1860 and AutoLumo A1880. Specific differences are stated as table below. This manual takes AutoLumo A1800 as an example to describe and illuminate. Unless otherwise stated, the descriptions in this manual are applicable to all of the models.

Difference Model	External barcode scanner	Automatic water emptying	Sample racks
AutoLumo A1800	Yes	Yes	24 pcs
AutoLumo A1820	No	No	18 pcs
AutoLumo A1860	Yes	No	24 pcs
AutoLumo A1880	No	Yes	18 pcs

### 2.1 Structure Composition

The instrument is composed of sample management unit, reagent management unit, reaction vessels loading unit, sample/reagent adding unit, incubating unit, cleaning metering unit, mixing unit, gripper unit, circuit control unit and liquid path unit.

Accessories include sample rack, sample cup, reaction vessels, system wash container, waste box, purified water container, wash buffer container, and waste liquid container.



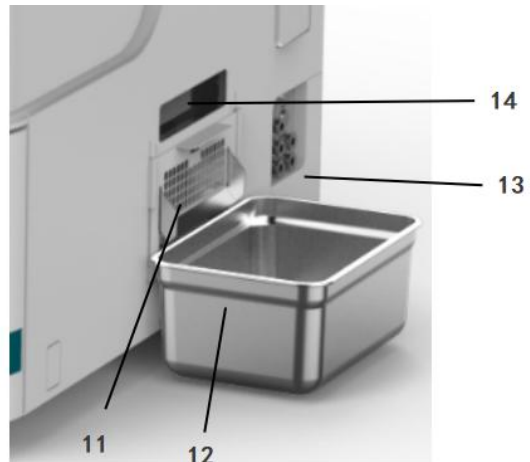
Appearance

Layout description 1

No.	Name	No.	Name
1	Upper lid	2	Reagent carousel cover
3	Substrate door (left front door)	4	Sample door (central door)
5	Reaction vessel door (right front door)	6	CE cover
7	Solid waste container	8	Observation window of Magnetic wash suction pump



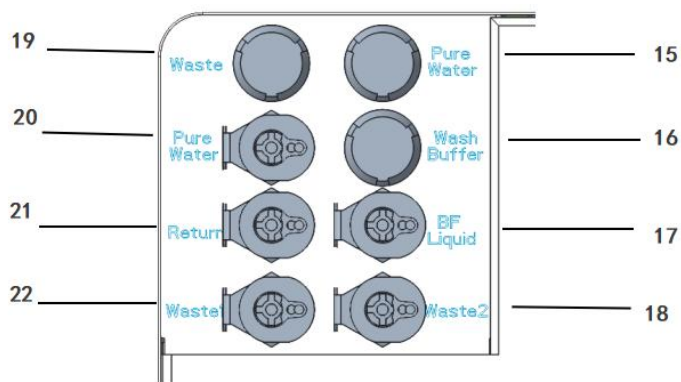
Instrument left panel



Instrument right panel

Layout description 2

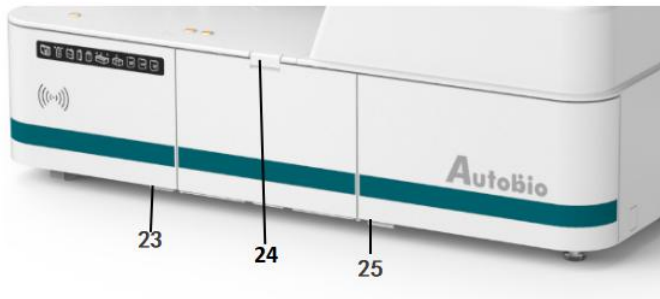
No.	Name	No.	Name
9	Upper lid lock	10	Power panel
11	Rat guard	12	Solid waste container
13	Liquid pipeline panel	14	Waste observation window



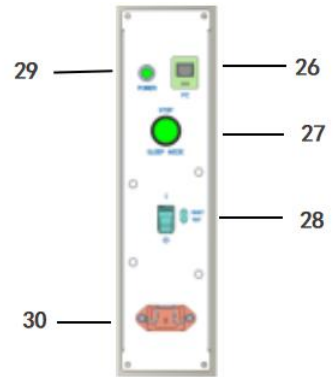
Liquid pipeline panel

Layout description 3

No.	Name	Application	Category
15	Pure Water	For purified water container liquid level detection (anti-liquid shortage)	Float switch interface
16	Wash Buffer	For BF wash buffer container liquid level detection (anti-liquid shortage)	Float switch interface
17	BF Liquid	For BF wash buffer container tube connection	Liquid pipeline interface
18	Waste 2	For waste liquid tube interface 2	Liquid pipeline interface
19	Waste	For liquid level detection of waste liquid container (overflow prevention)	Float switch interface
20	Pure Water	For purified water tube connection	Liquid pipeline interface
21	Return	For excess purified water reflux	Liquid pipeline interface
22	Waste 1	For waste liquid tube interface 1	Liquid pipeline interface



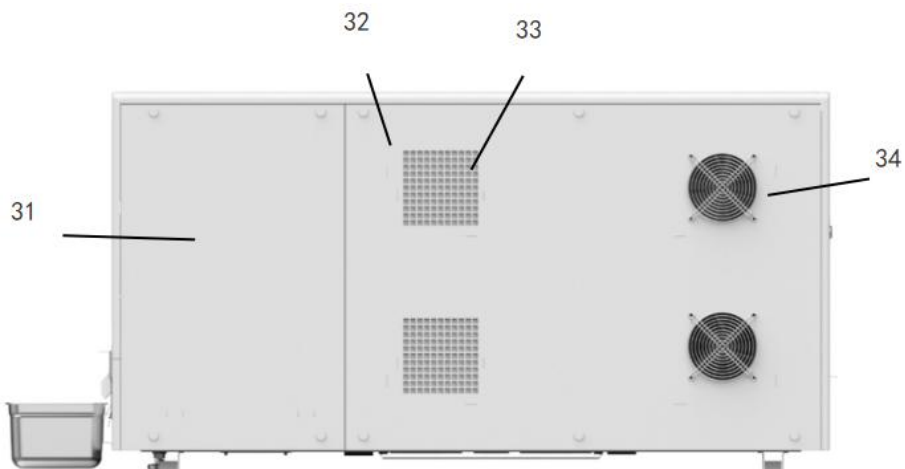
Front door



Power supply panel

Layout description 4

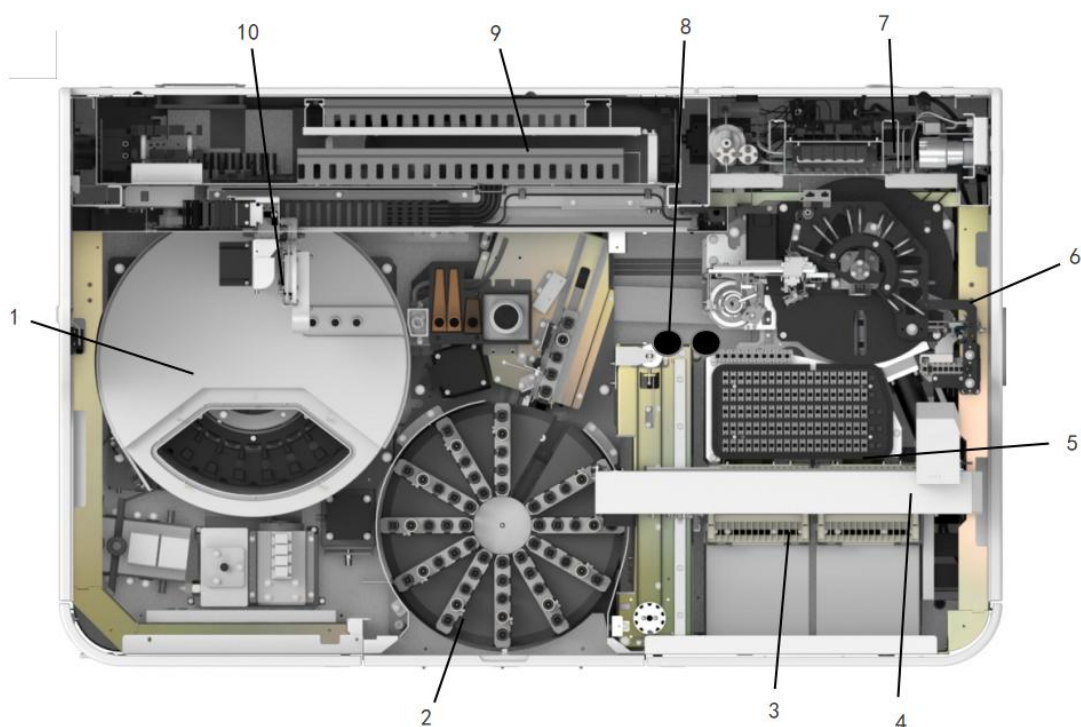
No.	Name	No.	Name
23	Left front door button (for opening doors)	24	Central door button (for opening door)
25	Right front door button (for opening doors)	26	Network interface (PC)
27	Independent cooling/stop button (SLEEP MODE/STOP)	28	Instrument Power switch (I/O)
29	Power indicator (POWER)	30	Power socket



Rear of the Instrument

Layout description 5

No.	Name	No.	Name
31	Liquid pipeline panel	32	Panel of electric cabinet
33	Air inlet hole of electric cabinet	34	Cooling fan

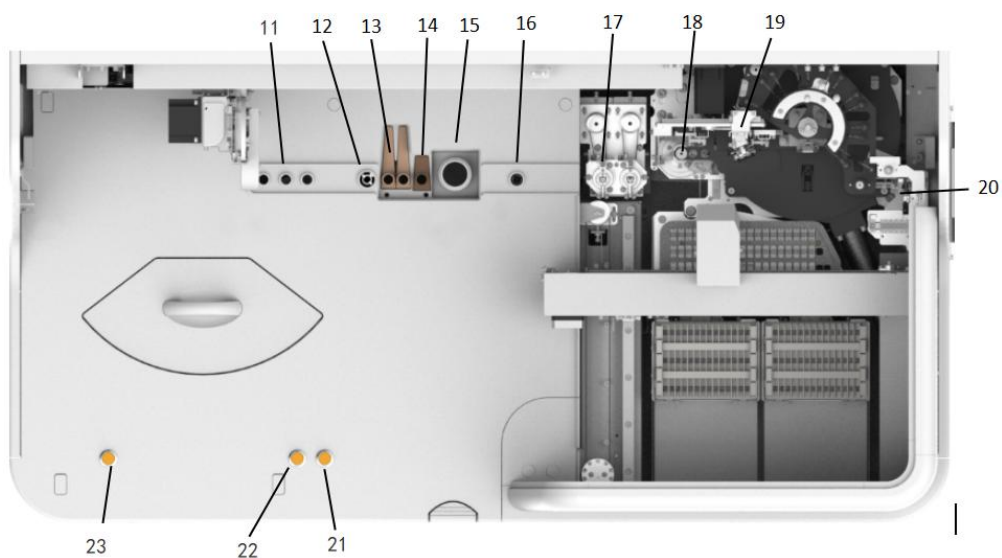


Internal structure

Internal structure description 1

No.	Name	No.	Name
1	Reagent management unit	2	Sample management unit
3	Reaction vessel loading unit	4	CE unit
5	Incubation unit	6	Cleaning & metering unit
7	Liquid pipeline unit	8	Mixing unit

9	Circuit control unit	10	Sample/ reagent adding unit
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Top view of panel

Internal structure description 2

No.	Name	No.	Name
11	Reagent loading position	12	Wash station
13	System wash bottle	14	Dilution bottle 1
15	Dilution bottle 2	16	Sample position
17	Sample and reagent mixing tip	18	Substrate mixing tip
19	CE2	20	Solid-liquid separation position (external)
21	Sample rack turntable button/indicator (SAMPLE TURN)	22	Emergency button (STAT)
23	Reagent carousel order/turn button/indicator (REAGENT ORDER / TURN)	/	/

**Reagent management unit:**

**Function:** It's for fixing reagent kits, switching the reagent slot driving mixing of magnetic bead bottle, low-temperature storage of kit, reading and writing of reagent information, reagent taking and putting order, and displaying the working status of this unit.

**CAUTION:** Do not open the cover of the reagent carousel when the order indicator is on. Make sure the kit is installed properly, and close the cover of reagent carousel after replacing or loading the reagent. Verify the correct relative position of the kit and probe after reagent installation or probe change.

**Sample management unit:**

**Function:** It's for sample rack buffering (loading in, loading off), reading bar code information of sample rack and sample tube eliminating static electricity from the sample tube, sample tube type judgment, sampling line jam judgment, and the unit operating state indication function.

**CAUTION:** The sample rack should be installed in place, the sample tube should be inserted into the bottom of the sample rack, the bar code of the sample tube should be directly grooves on the sample rack, the sample button indicator state should be confirmed when taking and putting the sample rack, and the central door should be closed after putting the sample rack.

**Reaction vessel loading unit:**

**Function:** Reaction vessel holder lock positioning, moving back and forth when changing the reaction vessel holder, in place detection, current working status indicator displaying.

**CAUTION:** Reaction vessel holder should be pressed to the end, the drawer should be pushed to the end, the drawer should not be pulled out when the indicator is on, and parallelism of gripper to this unit and the correct position of gripper should be checked during installation.

**CE unit:**

**Function:** According to the software instructions, the reaction vessel will be caught in the corresponding position, and it can judge whether the reaction vessel is grasped. For example, put the empty reaction vessel in the specified position and discard the old reaction vessel to the discarded position.

**CAUTION:** If it is newly installed or the disassembled unit, cleaning metering unit, incubation unit, mixing unit, and reaction vessel loading unit. It is necessary to confirm and debug the incubation unit and the reaction vessel loading unit in parallel with the gripper unit. The relative position of the reaction vessel and the gripper of the corresponding unit should be confirmed and adjusted.

**Incubation unit:**

**Function:** Reaction liquid heating, positioning storage to prevent rotation, reaction vessel



buffering.

**CAUTION:** Before the test, pay attention to the clearing of the incubation unit, and check the parallelism between the gripper and the unit and the correct position of the gripper and the cup.

**Cleaning & metering unit:**

**Function:** Repeatedly rinsing and separating the specific binding from the unreacted free component, retention of specific components, adding and mixing substrate to stimulate luminescence, incubation, photon counter photometry, waste liquid and reaction vessel solid-liquid separation, and reaction vessel discarding into the waste box (solid waste bin).

**CAUTION:** Before the test, the initialization should be normal, the positioning of the gripper unit and the inlet and outlet of the cup should be accurate, and the detection of the gripper and measurement of the instrument assisted routine light source should be normal.

**Liquid pipeline unit:**

**Function:** Providing fluid related system driving, extraction and infusion of sample, reagent, and diluent solution, realizing the flushing function of probe and pipeline, and storage function of system liquid.

**CAUTION:** The consumables should be replaced in time when the alarm is displayed on the client.

**Sample mixing unit:**

**Function:** Sample dilution mixing, sample adding reagent mixing, reaction vessel positioning anti-rotation.

**CAUTION:** Only after the initialization is successful can the test and installation be carried out to check the correct position of the gripper and cup.

**Circuit control unit:**

**Function:** Power supply for the instrument, connecting of instrument host with the computer for communication, controlling of of each sub-circuit function realization, motor pump valve and other output drive control, sensor and other input signal detection.

**CAUTION:** Comply with the relevant safety precautions. For details, refer to the Service Manual.

**Sample/reagent adding unit:**

**Function:** Quantitative extraction and infusion of sample, diluent solution, and reagent. . Anti-leakage adding liquid level detection, empty pumping block probe judgment. Clear the inner and outer wall of the probe against carrying pollution.

**CAUTION:** Do not open the big clamshell when the machine is working to prevent damage to the probe, or the instrument causes injury to the operator.

**Accessories:** Including sample rack, sample tube, reaction vessel, diluent bottle, system wash container, waste box, purified water container, wash buffer container, and waste liquid container, etc.,.

The system test is divided into three modes: continuous test, random test and emergency operation. The test can be started after the samples are put into the sample management unit in mode of continuous test or random test. The emergency samples should be put into the emergency tank of the sample management unit for test, and the emergency samples will be prioritized for test.

The instrument has an independent software system (application software), can only be used with magnetic particle chemiluminescence reagent series of Autobio.

Please use the kit in strictly accordance with the instructions of relative products.



Only to ensure that each part is in the ready state, the system can be used for normal test and analysis!



When using this product, a clinical diagnosis should not be made on the basis of the results of a single assay alone, but only after the physician has evaluated all clinical and laboratory tests.

## 2.2 Intended Purpose

Automatic Luminescence Immunoassay Analyzer is strictly intended for professional In-vitro Diagnostic use. It is a fully automated instrument which is clinically used for qualitative and quantitative assay of analyte derived from human serum, plasma or urine samples, such as tumor-associated antigens, liver disease, hormones, infectious diseases, immune function, autoantibodies, proteins and peptides, cardiomyopathies, vitamins, amino acids and blood concentrations, allergens, other enzyme and kidney disease and so on.

Authorization: The operating manual and the operation of the Automatic Luminescence Immunoassay Analyzer are to be only used by authorized or professionally trained personnel.

Contraindication: None.

## 2.3 Working Principle

Automatic Luminescence Immunoassay Analyzer adopts both chemiluminescence technology and magnetic particle separation technology. The main principle of detection is antigen/antibody coated magnetic particles are immunoreactive with enzyme-labeled antigen/antibody conjugate to form various antigen-antibody - antigen/antibody complexes to be detected - enzyme-labeled antigen/antibody complexes. The complexes

catalyze the luminescence substrate to emit photons, the photon energy is recorded using a photometer, and the light energy intensity is converted to the concentration of the antigen/antibody to be detected by a computerized processing system on the standard instrument. The product is widely used in the detection of infectious disease markers, tumor markers, sex hormones, thyroid hormone and other important indicators.

## 2.4 Performance Parameter

Name	Automatic Luminescence Immunoassay Analyzer
Test speed	Max. 180 tests/hour
Sample carrier	5 sample sites/ rack
Sample cup type	Sample tube diameter 12 - 16mm, 2 ml microcup
Loading method	Single probe injection samples and reagents (with liquid level detection, air suction, blocked probe detection)
Sample size	60 samples (It can be added circularly, including the priority test lane for emergency samples)
Analyze items no. simultaneously	No more than 25 items
Reagent site	25
Reagent mixing	The magnetic particle reagent is continuously mixed
Item shielding	Yes
Dilution	Custom dilution and fixed dilution (maximum 51*51 times =2601 times)
Sample type	Serum, plasma, urine
Reaction vessel supply	80 reaction vessels/ rack, 2 racks at the same time, a total of 160 reaction vessels, supporting non-stop online addition
Probe cleaning	Surround type vacuum suction cleaning
Reactive mixing	Eccentric non-contact swirl mixing

Solid-liquid separation of reaction waste	Before and after the reaction, samples, reagents and reaction vessels were separated, treated and discarded
Substrate	It supports two sets of substrates at the same time, and supports automatic switch without shutdown, substrate preheating function
Retest	Support automatic retest function, automatic test associated items, over-limit automatic dilution retest
Magnetic bead cleaning system	Five - level swimming magnetic separation cleaning, independent magnetic separation cleaning system
Carry-over	Carry-over rate $\leq 10^{-6}$
Data processing mode	Four parameters, linear regression, logit-log, point to point
Instrument noise	Sound pressure: $\leq 70$ dBA when working; 65 dBA when idle
Temperature range of reagent zone	2~8 °C (Dormancy mode, reagent independent refrigeration energy saving)
Temperature range of reaction zone	Accuracy: 37 °C $\pm$ 0.3 °C; The fluctuation should be not more than 0.3 °C
Volume bias of sample probe	8 $\pm$ 1 ul, 150 ul $\pm$ 2 %
Volume bias of Substrate probe	50 ul $\pm$ 5 %
Coefficient of variation of each sub-injection probe	Sample probe: 8 ul, CV $\leq$ 5 %, 150 ul CV $\leq$ 2 %; Substrate probe: 50 ul, CV $\leq$ 3 %
Within-run precision of clinical items	Coefficient of variation (CV) $\leq$ 8%
LIS system	Support one-way, two-way LIS

## 2.5 Operation Environment

Operating environment requirements: This instrument must only be used in the room where the operation environment condition in the table below is sound:

Item	Requirement
Temperature	Normal operating environment temperature: 10°C ~30°C
Relative Humidity (RH) (non-condensing)	Normal operating environment humidity: ≤85 %
Altitude	≤2000 m
Ambient Brightness	Avoid direct exposure to strong light
Atmospheric Pressure	85 kPa ~106 kPa
Operating environment temperature change rate	2°C every 30 minutes
Pollution Degree	2
EMI	Stay away from sources with strong electromagnetic interference
Interference from other Instruments or Equipment	Away from high power, strong amplitude, strong light illumination instrument and equipment
Water quality requirements	Conforms to ASTM D1193 standard specification for reagent water

## 2.6 System Specification and Feature

### 2.6.1 Weight

Item	Weight
Instrument (before adding supply materials and samples)	183 kg
Computer	Refer to documents of manufacturer

## 2.6.2 Power Requirements

Component	Requirement
Instrument	Voltage: 100-230 V Frequency: 50/60 Hz Power Consumption: 1 .0kVA Voltage Fluctuation: No more than $\pm 10\%$ Overvoltage Category: II
Computer	Refer to documents of manufacturer

## 2.6.3 EMC information:

- 1) The instrument meets the emission and immunity requirements of EN 61326-1 and EN 61326-2-6;
- 2) The instrument was designed and tested according to the group I class A equipment in EN 55011;
- 3) It is recommended to evaluate the electromagnetic environment before using the instrument;
- 4) Do not use the instrument near high radiation sources (such as unshielded radio frequency sources), otherwise it may interfere with the normal operation of the instrument;
- 5) The instrument meets the requirements of EN 61326-1 and EN 61326-2-6. The radiation emission and terminal disturbance voltage limits meet the requirements of Group 1, Class A of EN 55011. If used in residential areas, please take the following protective measures (if you have any questions, please contact the manufacturer or local dealers):
  - a) Keep mobile devices away from the instrument;
  - b) A well-grounded three-hole socket shall be used;
  - c) Ensure that other equipment and the instrument do not use the same power connector;
  - d) Use fully shielded network cables;
  - e) Repositioning according to the requirements of the instrument.
- 6) Connecting external devices must meet the requirements of EN 61326-1 and EN 61326-2-6.

**CAUTION 1:** Autobio is responsible for providing customers or users with EMC information

of this instrument.

**CAUTION 2:** It is the responsibility of the user to ensure the EMC environment of the equipment to enable the normal operation of the instrument.



**WARNING:** This device is not intended for use in a residential environment where it does not provide adequate protection for radio reception.

## 2.6.4 Dimension

The following table lists the dimensions of the instrument and external equipment. Please refer to the table before installation.

Instrument with the upper lid and door closed	Length: 1200mm Width: 736mm Height: 635mm
Instrument with the upper lid and door opened	Length: 1375mm Width: 845mm Height: 1110mm
Space Required to Ventilation, Safety Operation and Maintenance	Back: 500mm Top: 600mm Front: 800mm Left: 200mm Right: 800mm
Workbench	Width: $\geq 2000$ mm (instrument and computer on the same workbench) Width: $\geq 1400$ mm (computer table for computer, workbench for instrument) Height: $\geq 750$ mm Depth: $\geq 800$ mm The weight must be at least 750KG

## 2.6.5 Electrical requirements

This product complies with the safety requirements of IEC 61010-1 and IEC 61010-2-101. The power wiring terminal is grounded to prevent human body from electric shock. The

grounding terminal must be connected to the earth.

### 2.6.5.1 Power Supply

The power supply should meet the requirements of the following table in order to avoid damaging to the instrument.

Item	Requirement
Circuit Power Supply	AC 100-230 V, 50/60 Hz , single-phase power supply
Circuit Specificity	Special purpose (only for the connection between the instrument and the circuit)
Connector of Power Cord	AC250V, 10A
Power cord plug	AC250V, 10A
Power Cable	300/500V
Circuit Outlet	Not more than 2m away from the instrument, and compatible with the plug of the instrument
Voltage Fluctuation	No more than $\pm 10\%$ per cycle
Maximum Resistance between Instrument Ground Wire and Safety Grounding of Lab	Not more than 0.1 ohms

The power supply of the instrument requires three spliced power cables, and the ground cable of the power cable should be grounded in good condition. It is forbidden to disconnect the ground cable or bypass the ground cable. The instrument should be powered separately, do not share the power supply with computers, printers and other peripheral auxiliary products.



**CAUTION:** Improper connection of instruments and peripherals to power or damaged connection cables may result in serious personal injury and potentially fatal consequences and material damage (such as fire). Improper positioning (installation or operation) of the instrument or improper environment may cause fire or serious instrument damage because the instrument cannot be turned off or separated from the main power supply during operation.

### 2.6.5.2 UPS for the Instrument



If an uninterruptible power supply (UPS) is required as a backup power supply, Autobio recommends that you use a UPS with local grounding isolation and a low battery level indicator. You may contact the technical support department of Autobio for recommendation of backup power supplies.

The UPS power supply must meet the following requirements:

Item	Requirement
Minimum output capacity	2400VA
Output voltage	Range: 100-230V
Output frequency	50/60Hz
Output waveform	Sine wave
No load running time	At 1000VA, minimum 15 minutes
Certification	Complies with local certification standards



**CAUTION:** If it is necessary to power off the parts of the instrument, the equipment and the power supply should be disconnected.

### 2.6.5.3 Computer Configuration

The following table lists the minimum configuration requirements. The actual configuration must be no lower than the minimum configuration.

Item	Requirement
Operating system	Windows 10 or above
Processor	The main frequency is 1.8 GHz or above
Memory	4 G or above
Hard Disk	500 G or above
Display	Resolution: 1280 *1024
Database	SQL Server 2012 or above



**CAUTION:** The computer should conform to the specification of current version of N62368 -1.

## 2.7 Used in Combination with Other Products

This instrument is used with reagents produced by Autobio Diagnostics Co., Ltd.. End-user must read the manual of IVD kits carefully before usage to avoid unreliable assay result (such as expiration date, etc.).

This instrument supports the interaction of LIS data. In order to achieve this function, the customer's LIS engineer needs to implement the software interface according to the instrument's LIS communication protocol. The customer's LIS engineer should contact the technical support personnel of the instrument.



**CAUTION:** Due to failure to follow the kit instructions or attempt to use another company's kit, our company will not be responsible for the reported results.

Do not add any other instrument to the socket of the instrument except the instrument installed by the company's authorized representative.

## 3 Installation & Commissioning



The installation and commissioning of AutoLomo A1800 must be executed by service engineers or personnel authorized by Autobio. Do not take out the instrument from the package without the engineer presenting at the site. After installation, any other device can not be plugged in the socket connected with the instrument.

### 3.1 General

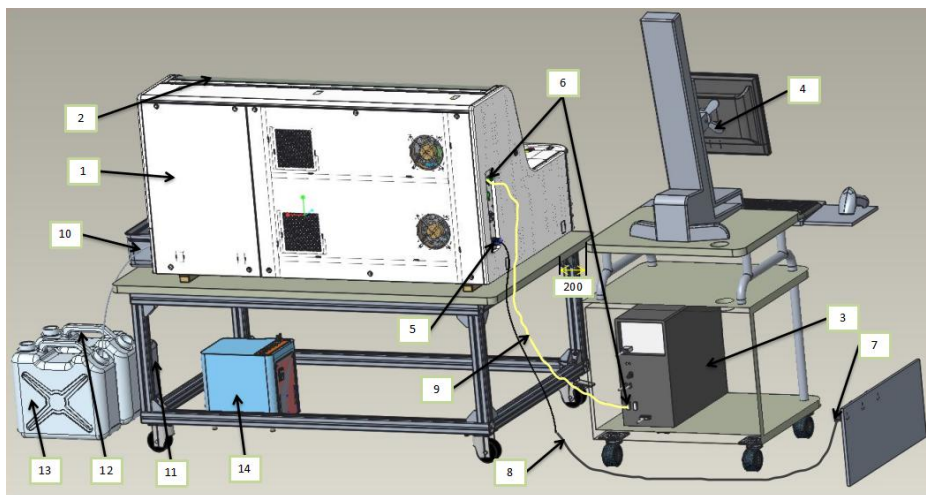
The instrument can not be installed and used in a laboratory with potentially explosive atmosphere. It can only be operated under the working conditions (temperature, altitude, no direct sunlight exposure and humidity) specified in this manual. End-user is obliged to assess whether the above requirement has been met.

### 3.2 Installation of Instrument Connection

Installation of this instrument must be performed by manufacturer or agent personnel. Do not take the instrument out of the package before the manufacturer or agent personnel arrives at you.

Connection of instrument to other equipment:

No.	Name	No.	Name
1	Instrument	2	Upper lid
3	Computer	4	LCD
5	Power panel	6	Computer port
7	Power strip	8	Power cord
9	Ethernet cable	10	Solid waste container
11	System wash container	12	Purified water container
13	Waste liquid container	14	Autofluid (optional)



### 3.3 Installation Precautions

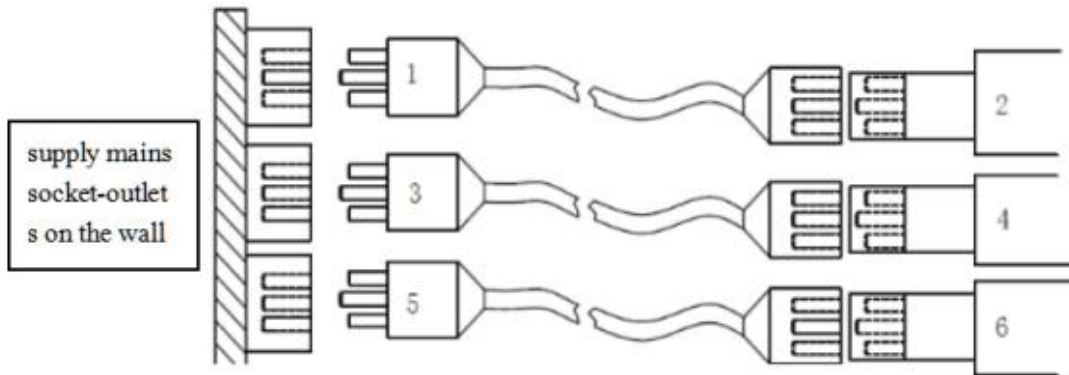
Precautions for instrument installation:

- a) The instrument shall be installed in accordance with the requirements of 2.6.4 workbench size.
- b) The instrument must be installed in a convenient position to operate the power switch.
- c) When the instrument needs to be transported or moved, service engineers from Autobio should be contacted for transportation or moving guidance.
- d) The side housing must be fully installed before the instrument is energized.
- e) To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth; If the instrument is moved, contact the manufacturer or agent to confirm the protective grounding of the instrument.
- f) If the equipment is not used in the way specified by the manufacturer, the protection provided by the equipment may be impaired.
- g) The instrument is connected with the computer by a communication line. The connection of the communication line should be in accordance with the corresponding connection of the label on the instrument and the computer.
- h) The instrument does not need to be leveled before use, but please confirm the level of the workbench by professional personnel.
- i) Ensure that all retaining hardware (e.g. screws, fasteners) are in place on enclosures, and the enclosures are in place on the instrument before normal operation.
- j) Ensure that the side housing of the instrument is closely fixed before switching on.

k) Do not use detachable mains supply power cord with inadequate rating.

l) After the instrument clamshell is locked, professionals should keep the instrument clamshell key to avoid injury.

Please connect the power cable according to the following:



Cable Connection Diagram

1: Instrument power plug	2: Instrument
3: Computer power plug	4: Computer
5: LCD power plug	6: LCD



**CAUTION:**

When installing waste liquid tubes, use only standard tubes. Do not connect other tubes without permission.

The company shall not be liable for any injury or loss caused by the use and connection of the instrument by personnel not trained or authorized by the Company.

Unauthorized personnel shall not install and service the instrument or change the installation without the approval of the Company;

It is strictly prohibited to change and/or modify the conditions and functions of the instrument clamshell. When the instrument is in the special operating state of open cover maintenance, do not approach the moving parts or contact the moving parts with hands, arms, shoulders or face/head.

After the device is moved, contact the manufacturer or agent to confirm the status of the device in time to avoid damages to the suction probe or irregular suction caused by system abnormalities.

Replaced instruments, packaging materials and all components must be handled in accordance with applicable local and national laws, regulations and laboratory procedures.

Please check whether the power cord is damaged before use.

Please clean the dust on the plug regularly to avoid danger.

### **3.4 Commissioning**

The commissioning of the instrument must be performed by service engineers from Autobio or agent.

Users are not allowed to debug, please refer to the *Service Manual* for details!

## 4 System Operation

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The system can normally carry out a test from switching on the system to switching off the system provided that the operator definitely observes the operating manual when running the instrument.

### NOTE:

Refer to chapter 1.1.5-1.1.10 for all potential safety hazards when performing the instrument. Do not perform any operations or functions not described in the operating instructions. If trouble occurs on the diagnostic system, contact Autobio or an authorized representative in the distributed area. In the case of unreasonable or unforeseeable usage, it will cause erroneous assay result, damage to the system or personal injury.

Prior to operation, user should consult the operating manual, which must be followed strictly in case of damage to the analyzer.

### 4.1 Function Introduction

#### 4.1.1 System Description

Autobio Automatic Immunoassay Control System is used to control the work of the instrument. The software is divided into 9 parts: sample management module, calibration module, quality control module, consumable module, system setting module, printing module, test result module, maintenance module and diagnosis module.

#### 4.1.2 System Status and Control

##### 4.1.2.1 Start the Software

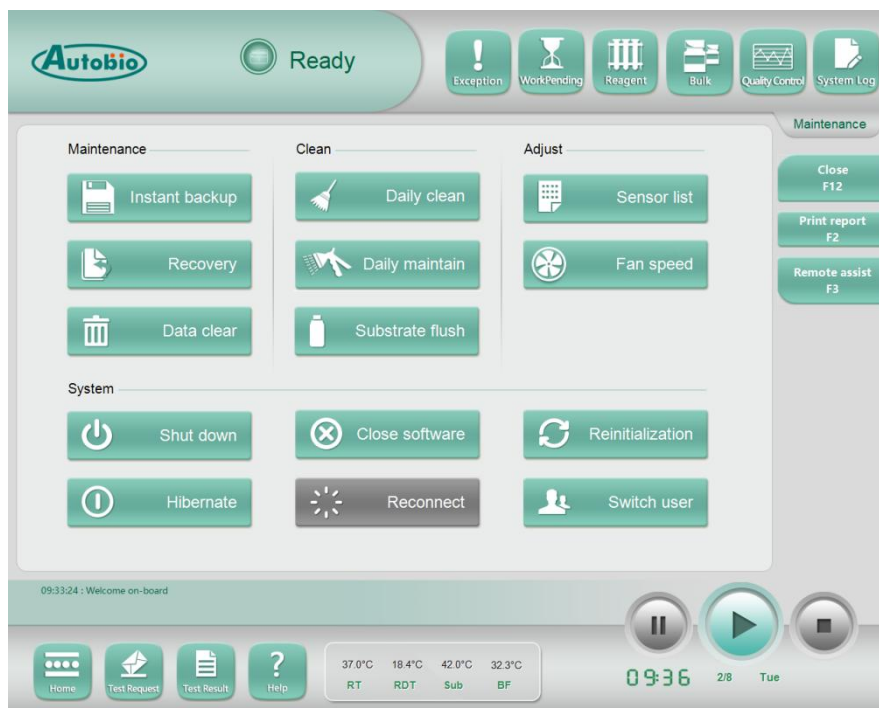
Click the shortcut icon of “AutoLumo A1800” on the desktop to start the software.



After the software starts, the main interface is displayed as below:



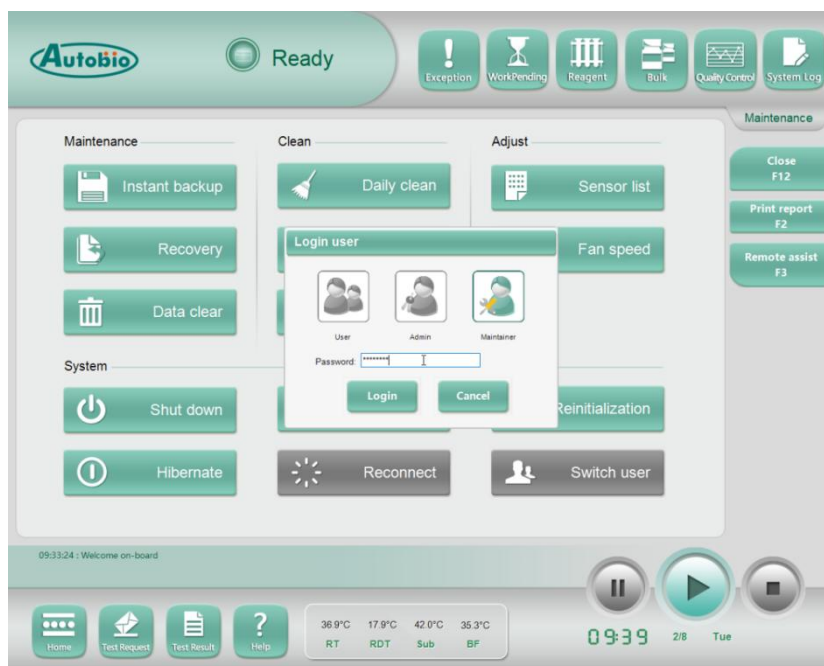
Click “Maintenance” to enter the secondary interface



Click “Switch User”, and the three user names in the dialog box will pop up (the permission



is explained below). Select the user with the corresponding permission and input the password (the details are provided by customer service).



The rights of software users are divided into three levels: operator, administrator, and maintainer. When the software starts, the default rights are operator.

**Operator rights:** routine application operations of the system, including maintenance, sample testing, calibration, quality control, reagent consumables status and log viewing.

**Administrator rights:** includes operator rights, diagnosis history, LIS setting, software information viewing, project parameter viewing, system backup, system restoration, administrator password change and other functions.

**Maintainer rights:** The maintainer can modify hardware parameters, configuration parameters, alarm settings, unit adjustment, and maintainer password, etc.,.

#### 4.1.2.2 State Indicators

The instrument has five states to display. The current status is displayed in the upper left corner of each interface. The three control buttons at the bottom right of the interface can be used to start the test, pause the injection, and stop the test for operation control.









System state	Description
Ready	The system is ready for normal operation.
Running	The system is running.
Pause	No new tests are planned, but currently planned tests will continue.
Not ready	The system is not ready and must be “Reinitialized” before any other operations can be performed.
Offline	The software is in a state of disengagement from the instrument.

### 4.1.2.3 System Shortcut Button

There are six shortcut command buttons. Under normal operating conditions, the button is green. Select a button to view the related interface. The button color changes in the following cases: the remaining availability of supplied materials requires attention, problems with sample handling, or the event log reports warnings or exceptions. The button will flash in yellow or red. The button will not return to the normal state until you select a button and check the alarm data or the alarm processing is complete.

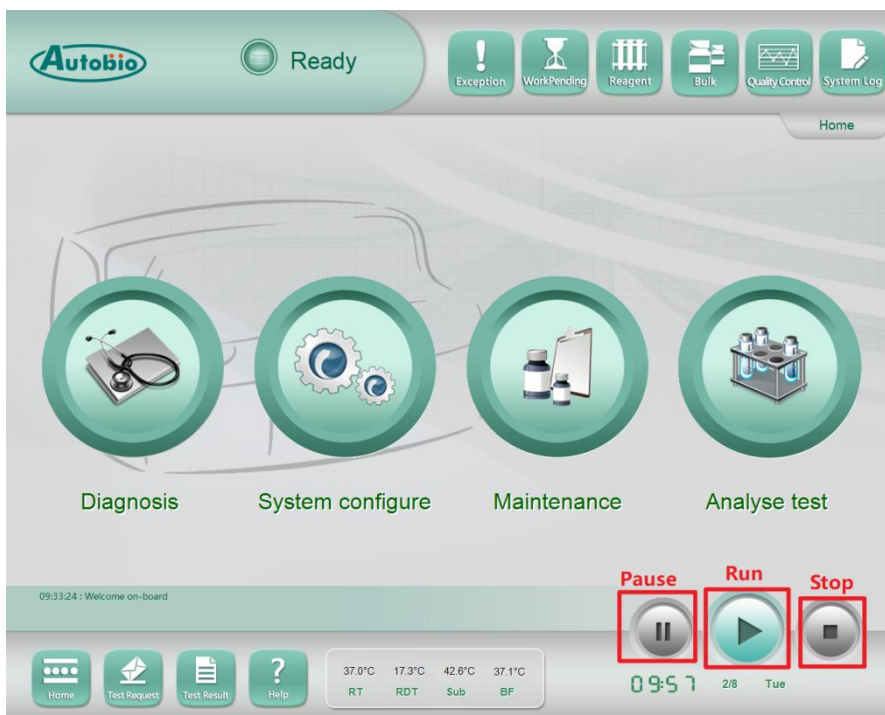





Shortcut button	Description	Button color and description
	<p>This command is used to select the Abnormal Detection queue view on the sample management page to view the abnormal sample detection request information. If the number of exception detection queues is empty, the button displays a normal color.</p>	<p>Red</p> <p>An exception occurred during the detection of one or more detection requests.</p>
	<p>This command is used to select the “Work Pending” queue view displayed in the sample management interface and view the sample detection request information in the work pending. If the number of work wait queues is empty, the button displays the normal color.</p>	<p>Yellow</p> <p>A work pending was caused by a test request that cannot be performed for some reason.</p>

	<p>This command is used to select display supply management interface for information about required supply reagents and calibration.</p>	<p>Yellow</p> <p>The system needs to be supplied materials or be scaled in order to complete the requested test.</p>
	<p>This command is used to select the display large-capacity consumables management interface to understand the amount of substrate, lotion, diluent, and reaction vessels available, as well as the space available in solid waste containers and waste liquid containers. If the consumable's remaining availability is in the normal state, the button displays the normal color.</p>	<p>Yellow</p> <p>Substrates may be about to expire, consumables are low, or waste liquid containers will be full.</p> <p>Red</p> <p>Substrates were expired, consumables were insufficient, or waste liquid containers are full.</p>
	<p>This command is used to select the display quality control product settings management interface to set the quality control product, or check the quality control product results. If the latest quality control test result is normal, the button will display the normal color.</p>	<p>Red</p> <p>The quality control result is not within the acceptable expected value range.</p>
	<p>This command is used to display the event log management page to learn about the events generated by the system. The alarm or warning event troubleshooting information is displayed on this screen. If the log warning event is viewed, the button displays the normal color.</p>	<p>Yellow</p> <p>The system generates a general warning event indicating a situation that requires your immediate attention.</p> <p>Red</p> <p>The system generates a critical warning event indicating a critical fault or error condition.</p>

### 4.1.2.4 System Control Button

The functions of the three system command buttons are pause, run and emergency stop.



Control button	Description
	<p>When the system is running or paused, the button is used to choose to stop the detection operation. After clicking the button, the system will stop processing and cancel the ongoing detection. Please confirm your choice before performing this operation.</p> <p> <b>CAUTION:</b> When an emergency stop operation is selected, all detection requests in operation, including those that have entered the sampling line, are stopped.</p>
	<p>When the system is running, it is used to suspend the detection operation. After clicking the button, no new tests are planned after the scheduled tests have been completed, but the samples that have started processing continue.</p>



When the system is in the ready or paused state, click the button to start or resume the detection operation.

 **CAUTION:** Precautions for starting the test in the ready state:

When the available number of reaction vessels, the amount of washing liquid, the available space of solid waste containers and waste liquid containers, diluent, the remaining volume of system wash and the remaining times of substrate are small, only part of the test can be done;

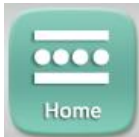


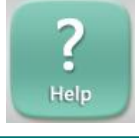
Before the experiment, please ensure that the dilution amount is sufficient, otherwise, the operation of diluent addition will not be carried out when the experiment is carried out;

If the temperature of the incubating tray, the temperature of the reagent carousel, the temperature of the substrate and the heating temperature of the cleaning & metering unit did not reach the normal range, the detection could not be started.

#### 4.1.2.5 Description of other Buttons and Their Status



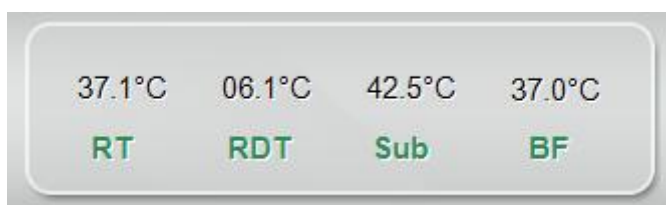
Other buttons	Description
---------------	-------------

	<p>Click this button to return to the main interface</p>
	<p>Click the button to enter the test request interface</p>
	<p>Click the button to enter the test result interface</p>
	<p>Click this button to provide a system help description</p>

1) Time display:



2) Temperature status display:



**Temperature status:** Normal/green, General Warning/yellow, Critical warning/red.

1) When the instrument is in the ready state and displays the general warning or the critical warning, the instrument does not perform the operation of adding samples. The corresponding operation can be performed only when the temperature display is normal.

Ensure that all parts of the instrument have stopped running.

2) In the running state of the instrument, when the general warning is displayed, the instrument will pause the sampling operation, and the ongoing detection will continue to be executed, but the test results will show the flag of relevant alarm information.

3) When the instrument is in the running state and a critical warning is displayed, the instrument will stop processing and cancel the ongoing detection.





**CAUTION:**

Before performing the test, ensure that the temperature sensor is working properly.





**WARNING:**

Observe the temperature change of the heating of the reagent carousel, incubating tray, substrate probe and cleaning & metering unit. If there is any abnormal situation (the heating of the reagent carousel, incubating tray, substrate probe and cleaning & metering unit does not change toward the set temperature), the power supply of the instrument should be disconnected immediately for troubleshooting.

### 4.1.3 Operation Mode

The operation mode of the instrument system is divided into the following two types:

System model	Description
	<p>Online mode: The system is in online mode, and there is no need to edit the test in the instrument system, and the sample rack is directly placed in the sample loading area. The instrument can obtain the sample information and test request data from the LIS system by communicating with the LIS system (laboratory information system) according to the sample number (bar code) or sample location read by the instrument.</p> <p>Enable method: [System Settings] - [LIS Communication Settings] - [Receive LIS request] - [LIS interface], select [Enable].</p>
	<p>Standalone Mode: The system is in standalone mode. Manually input sample data and assay request information through the operation interface.</p> <p>Enable method: [System Settings] - [LIS Communication Settings] - [Receive LIS request] - [LIS interface], select [Close].</p>

**NOTE:**

In the online mode, the system can read the manually entered sample data and assay request information, and can also obtain from the LIS system.



**Prompt**

In standalone mode, if the sample number (bar code) fails to be read in online mode, the sample number can be entered manually, and then the sample data and assay request information can be obtained from the LIS system through the function of “Obtaining LIS



Request”(in system setting, the LIS communication switch must be set to “ON”).

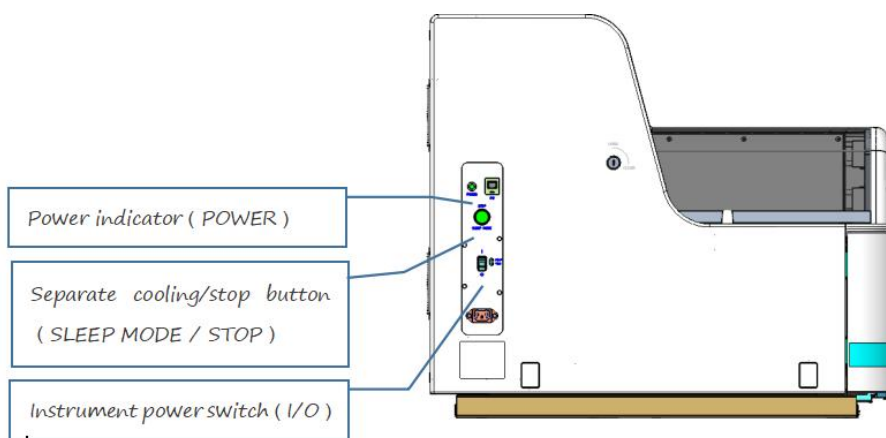
## 4.1.4 Shutdown and Restart

During the operation of this instrument, you may occasionally need to turn off the computer or instrument. The following steps describe how to properly shut down and restart a computer or instrument.

### WARNING:

Shutting down and restarting a computer or instrument must follow these steps, or you may damage the instrument or destroy the system database. Instruments and computers must be shut down or restarted in a “Ready” or “Not Ready” state!

### 4.1.4.1 Shutdown the Instrument

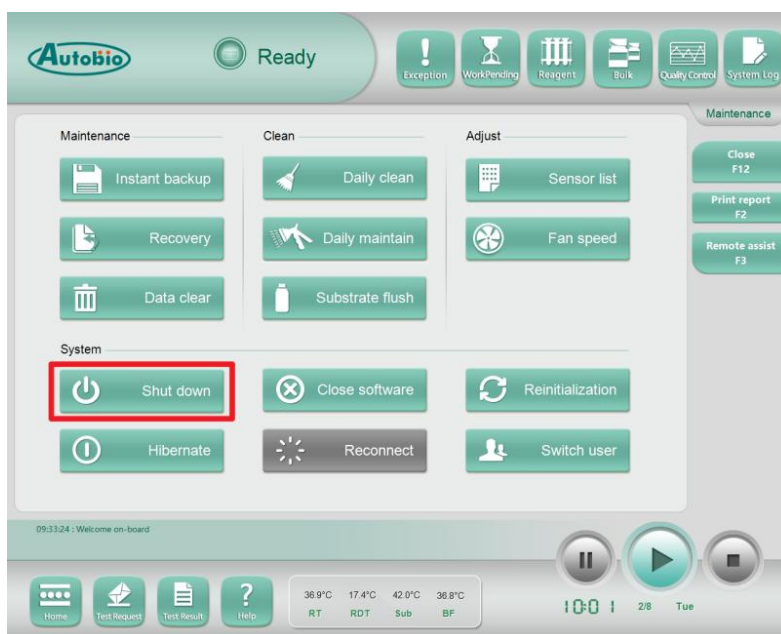


Press the “I/O” button in the left power panel to turn off the power of the instrument. At this time, the power indicator is off, indicating that the instrument has been turned off, and the status of the software interface becomes offline.

When the instrument is powered on, press the “SLEEP MODE/STOP” button, and the button light is steady on, indicating that the reagent management unit is in the state of power-on refrigeration, and the power indicator of the instrument is off, indicating that other units are in the state of power failure.

### 4.1.4.2 Shutdown the System

This function is unavailable when the state of the instrument is “Running” or “Pause”. Click the “Maintenance” button on the main interface to enter the maintenance interface, and then click “Shut down”, the computer will be shut down.



#### 4.1.4.3 Close the Software

This function is unavailable when the state of the instrument is “Running” or “Pause”. Click the “Maintenance” button on the main interface to enter the maintenance interface, and then click “Close software” to close the software.

#### 4.1.4.4 Long-term Shutdown of Instrument

If you plan to move the instrument or shut down the system for a long period of time (more than 5 days), before shutting down the system, contact the technical support personnel from Autobio to confirm the correct operation process. Please first execute the “BF Emptying” process, then execute “Close Software”, “Shutdown Computer” and “Shut down Instrument”. If the system is shut down for a long time and is to be stored for a long time, it is necessary to flush the system with purified water and then drain it. The specific procedures are as follows:

##### Automatic emptying function:

- 1) When the instrument is in the “Ready” state, click “Diagnosis” → “Load water empty test” → “Automatic” → “Empty” → “Execution”.
- 2) The instrument performs the pump back of the channel substrate in use, and the software has corresponding prompts.
- 3) After the completion of the pump back, take out the substrate bottles of the two channels according to the software prompts, seal and mark the channels and store them. Install the substrate bottles with purified water at the two substrate channels, and change

the liquid in the wash buffer container into purified water. After completion, confirm on the software and proceed with subsequent actions.

4) The instrument performs the water loading action (the tube line is filled with water). After this action is completed, pull out the suction probe of the substrate bottle according to the software prompts, pour out the wash buffer and the liquid in the purified water container and install the container back to the original position. After completion, confirm on the software, and continue the subsequent action.

5) After the instrument completes the emptying action, the software prompts that the emptying is complete. If there is no liquid filling in the sample adding probe tube, magnetic washing tube and substrate transparent tube, it means that the automatic empty function is completed.

#### **Manual emptying function:**

Similar to the automatic emptying function, it is necessary to manually input the number of perfusion and emptying, and manually confirm the emptying status. If the process is incomplete, you need to continue with the action.



#### **WARNING:**

During these steps, you will be exposed to potentially infectious materials. Handle and dispose of these biologically hazardous materials in accordance with proper laboratory procedures. Proper protection must be taken for hands, eyes and face.

#### **4.1.4.5 Daily Shutdown the Instrument**

Turning off the instrument will turn off the refrigeration in the reagent storage area.

- 1) Ensure that the current instrument status is “Ready”, “Not Ready” or “Offline”.
- 2) Run daily maintain program.
- 3) Remove all sample racks and sample containers from the sample supply unit.
- 4) Remove and refrigerate all kits.
- 5) Clean up large-capacity waste liquid containers.
- 6) Clear solid waste containers.

Turn off computers and instruments, including turning off power switches of instruments and computers.

#### **4.1.4.6 Hibernate**

In sleep mode, the instrument enters the power saving mode and only supplies power to the refrigeration system to keep the refrigeration system working normally while other components stop working. Sleep mode is the power off independent cooling mode.

Start sleep mode the software interface:

- 1) Ensure that the current instrument status is “Ready”.
- 2) On the main menu, choose “Maintenance”.
- 3) Select “Hibernate” on the maintenance interface.
- 4) Select “Yes” in the confirmation window.

Click the “Sleep Mode/Stop” button on the power panel.



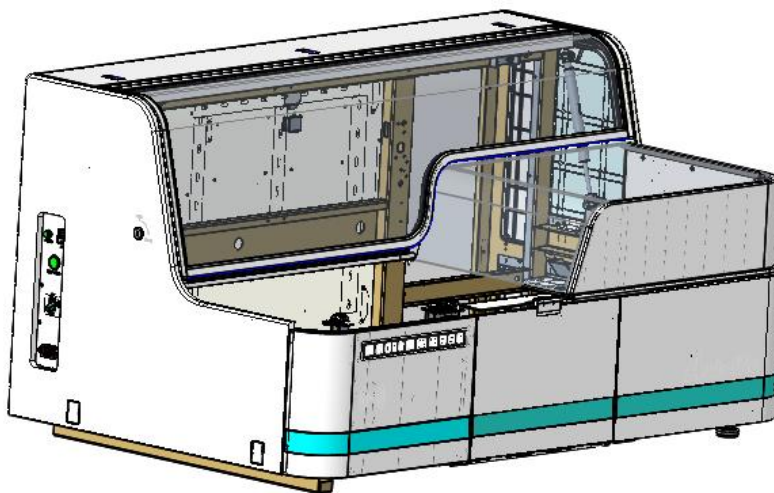
**CAUTION:**

Before executing, ensure that the instrument is not in the “Running” state, that is, in “Ready” or “Not ready” state. Otherwise, it may cause sudden power failure during the test of the instrument, resulting in damage to the instrument!

**4.1.4.7 Restart instrument**

Use the following steps to restart the instrument.

- 1) To the left of the instrument, facing the rear of the instrument, pull down and lift the instrument “Power Panel” “Air Switch”.
- 2) The power indicator of the instrument is on, indicating that the instrument has been turned on.



**Prompt**

- 1) After the computer is started, the system software interface is in the “Not Ready” state.
- 2) Confirm that the large clamshell cover of the instrument is closed.

3) Confirm that the “Air Switch” on the “Power Panel” is on, and the power indicator is on. At the same time, ensure that the SLEEP MODE/STOP indicator is off. If the indicator is on, it indicates that the device is in SLEEP MODE. You need to press the “SLEEP MODE/STOP” indicator, at this time, when the indicator is off, the instrument starts up;

4) If the computer is not running, please start the computer and the display, and start the instrument system.

Start the user interface software and perform Reinitialization on the maintenance interface.

a) Wait for the system to restore its internal temperature. If the instrument is turned off for a short time, the system will recover the internal temperature in 15 to 20 minutes. Do not open the clamshell until all temperatures have reached the desired range.

b) Verify that the system is in the “Ready” state. If the system temperature cannot enter the Ready state for a long time (about 60 minutes) after normal operations, contact the manufacturer or agent.

#### 4.1.4.8 Restart the System after a Long Period of Shutdown

After long-term shutdown, please use the following steps to restart the instrument system.

1) Start the instrument.

2) Start the computer and the instrument system.



#### **WARNING:**

During these steps, you will be exposed to potentially infectious materials. Handle and dispose of these biologically hazardous materials in accordance with proper laboratory procedures. Proper protection must be taken for hands, eyes and face.

#### **NOTE:**

Wait for the system to restore its internal temperature. Because the system was shut down for such a long time, it may take an hour for the system to restore its internal temperature. Do not load the sample reagent and open the cover of the instrument until all temperature zones are in the desired range.

After the temperature of the instrument recovers, perform the following operations:

1) Replace and confirm that there is sufficient cleaning fluid supply. If the cleaning fluid is not available, replace the cleaning fluid.

2) Confirm that the waste liquid container is not full. If it is full or already full, empty the liquid waste container and solid waste bin.

3) Check the supply of reaction containers and add more reaction containers if necessary.

4) Load the new substrate bottle.

5) Load the required kit.

6) Carry out the “Daily Cleaning” procedure, and carry out the substrate flushing procedure, the substrate flushing times should be not less than 60 times.

## 4.1.5 Brief Introduction of the Function

### 4.1.5.1 Testing Analysis

Click the “Analyse Test” button on the main interface of the system software



Enter into “Analyse Test” interface, the interface provides sub-functions: [Test items], [Consumables], [Quality Control], [Calibration], [Test Request], [Test Run], [Calculation] and [Results Analysis].



## Interface description

[Test item parameters] Set and change item parameters;

[Test combination] Set the test combination, such as “Preoperative Eight Items”;

【 Consumables 】 Consumables management and reagent management;

[Calibration] Calibrator setting and instrument item;

[Quality control] Set the quality control products and control the quality of instrument items;

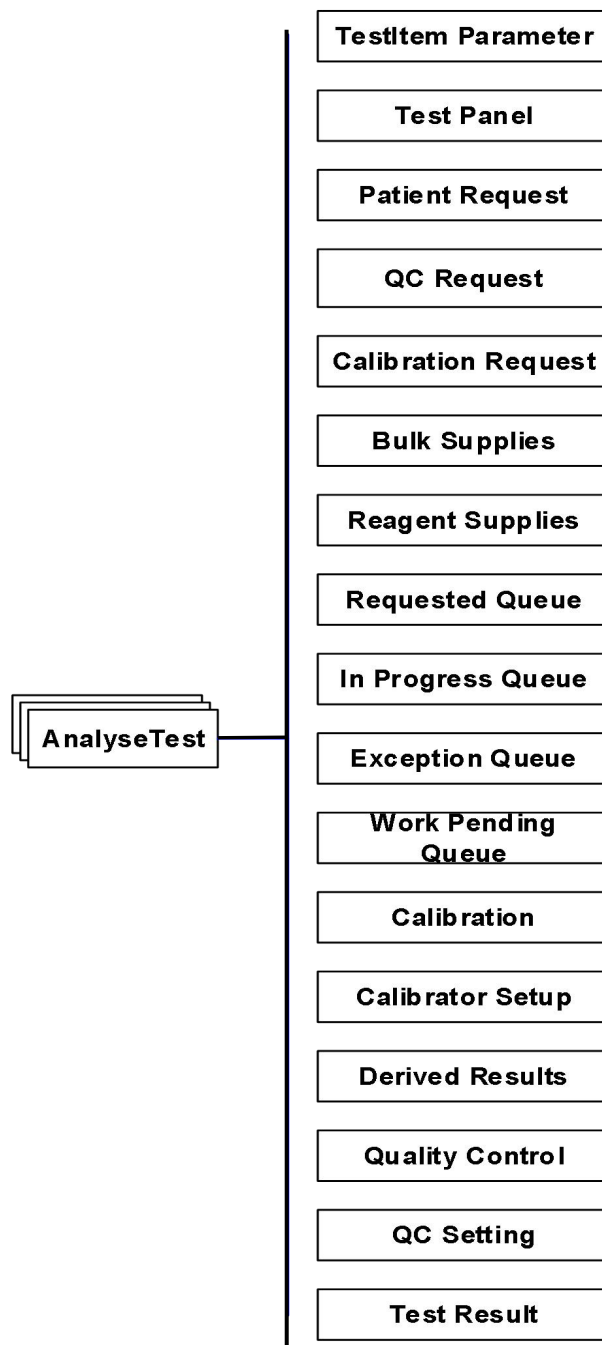
[Test request] Send samples for testing, calibration and quality control;

[Test run] Test [request queue], [Queue], [exception queue], [work pending ] status view and setting;

[Calculation] The project needs to adjust the setting and modification of relevant calculation formulas;

[Result analysis] Test result analysis and status query.

The menu contents are as follows:



Operation instructions:

1) [Test Item Parameters] operation

 **WARNING:**

It is not advised to modify the item parameters. By default, this permission is not granted to

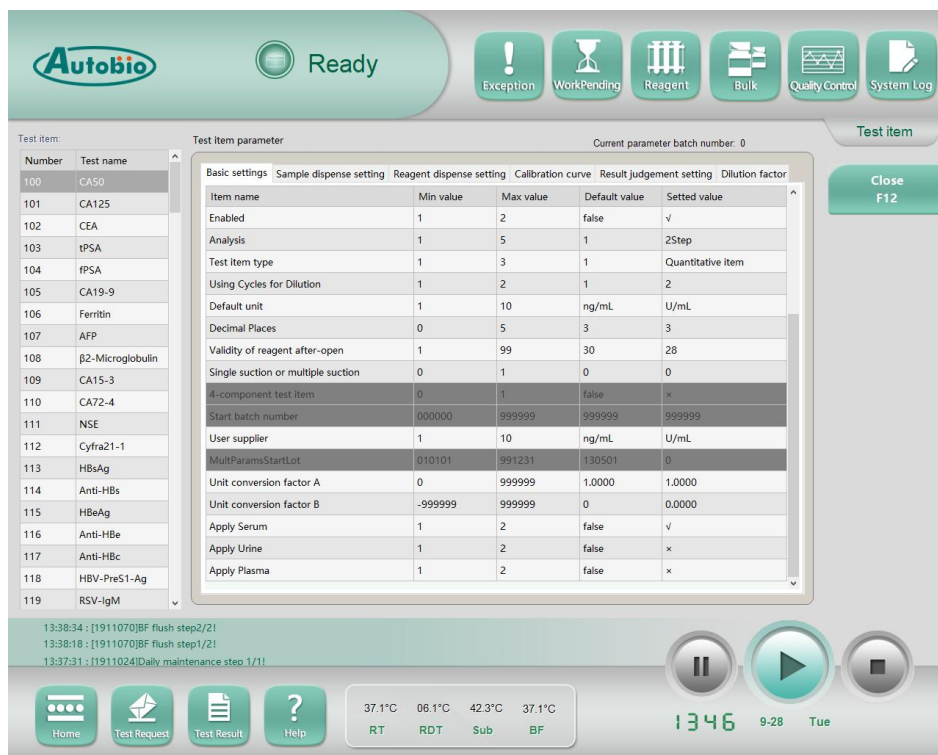


the user. The user only has the “Operator” permission. If there is any special requirements, please contact service engineer authorized by Autobio to operate. If the item parameters are modified by the user without permission of Autobio, the test results may be incorrect or unexpected result may occur!

Click “Test Item Parameters”:



Go to the following interface:



[Number] In the left menu bar indicates the code of this item in this instrument. Test results can be represented by item number 100 or test name CA50. The significance of this number can also be used to distinguish between different reagents used for the same test method or purpose.

Test item:

Number	Test name
100	CA50
101	CA125
102	CEA
103	tPSA
104	fPSA
105	CA19-9
106	Ferritin
107	AFP

Click the number [100] on the left to gray, and [Test Item Parameters] displayed on the right is the parameter content of the project number [100].

Autobio Ready

Exception Work Pending Reagent Bulk Quality Control System Log

Test item: 100 CA50

Test item parameter Current parameter batch number: 0

Item name	Min value	Max value	Default value	Setted value
Enabled	1	2	false	√
Analysis	1	5	1	2Step
Test item type	1	3	1	Quantitative item
Using Cycles for Dilution	1	2	1	2
Default unit	1	10	ng/mL	U/mL
Decimal Places	0	5	3	3
Validity of reagent after-open	1	99	30	28
Single suction or multiple suction	0	1	0	0
4-component test item	0	1	false	x
Start batch number	000000	999999	999999	999999
User supplier	1	10	ng/mL	U/mL
MultiParamsStartLot	010101	991231	130501	0
Unit conversion factor A	0	999999	1.0000	1.0000
Unit conversion factor B	-999999	999999	0	0.0000
Apply Serum	1	2	false	√
Apply Urine	1	2	false	x
Apply Plasma	1	2	false	x

Close F12

13:38:34 : [1911070]BF flush step2/21  
 13:38:18 : [1911070]BF flush step1/21  
 13:37:31 : [1911024]Daily maintenance step 1/11

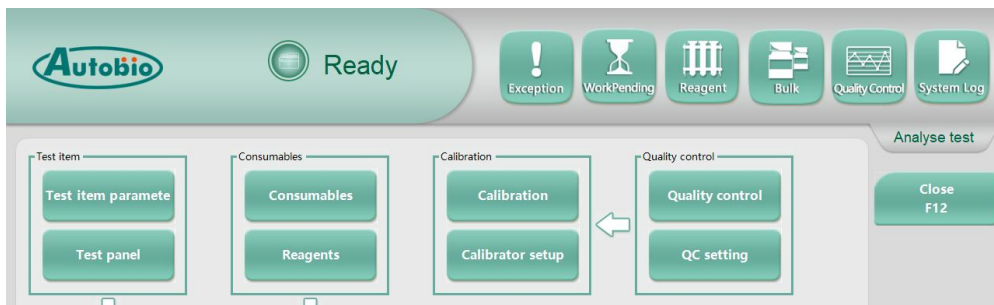
Home Test Request Test Result Help

37.1°C 06.1°C 42.3°C 37.1°C  
 RT RDT Sub BF

1346 9:28 Tue

2) [Test combination] is described in 4.8.3.

3) The [Bulks] button has the same function as the top [Consumables] button, as described in 4.7.



4) The [Reagent Management] button has the same function as the [Reagent] button on the top, which is described in 4.7.

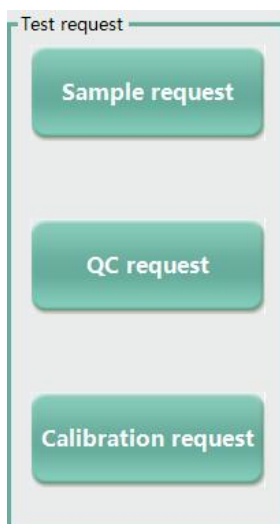


5) The “Calibrator Setting” button has the same function as the “Reagent” button in the upper right corner, as described in 4.5.1 and 4.5.2.

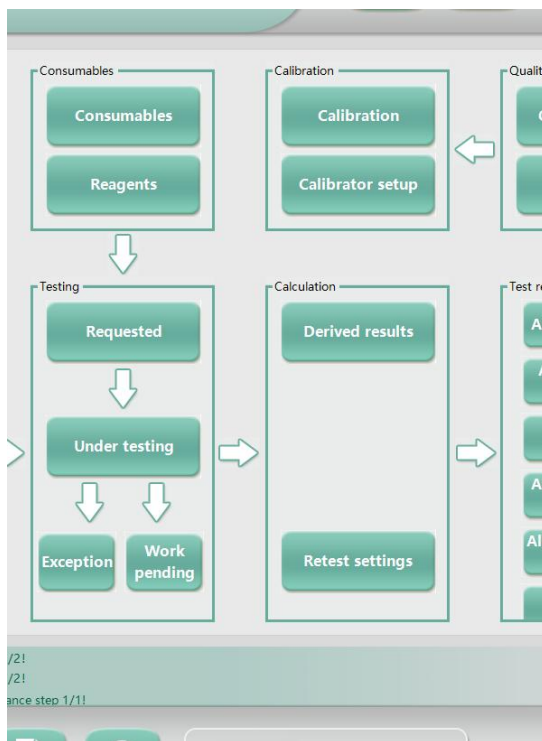
6) The “Quality Control Settings” and “Quality Control” buttons have the same function as the “Quality Control” buttons in the upper right corner, as shown in the figure below, as described in 4.6.1 and 4.6.2.



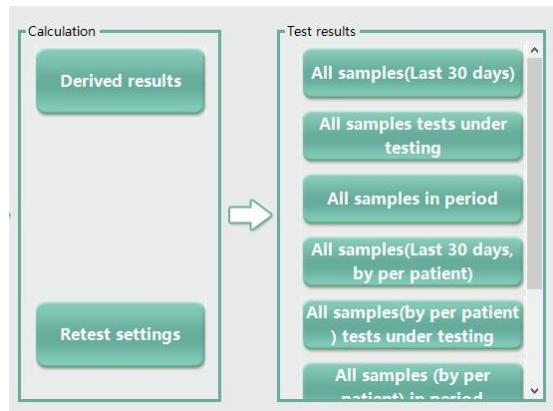
7) [Test Request] has the same function as [Test Request] button in the lower left corner, as shown in the figure below, as described in 4.2 [Patient Samples], 4.5.2 [Calibration] and 4.5.3 [Quality Control].



8) [Test Run] has the same function as the [Work Pending] button in the upper right corner, as detailed in 4.3.4.



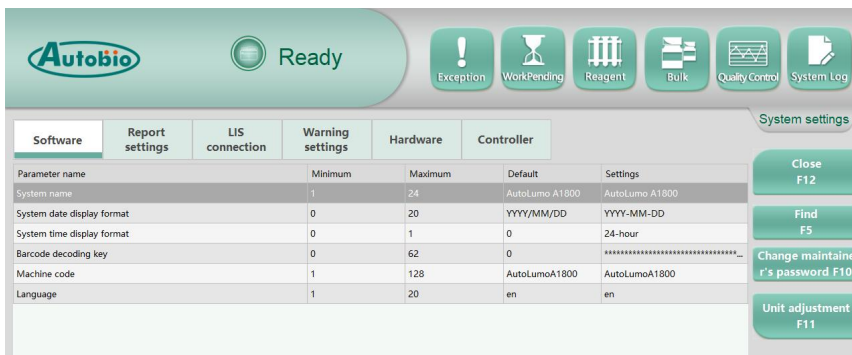
9) [Calculation] and [Result Analysis], which requires training on actual needs. The [Result Analysis] button is described in 4.4.



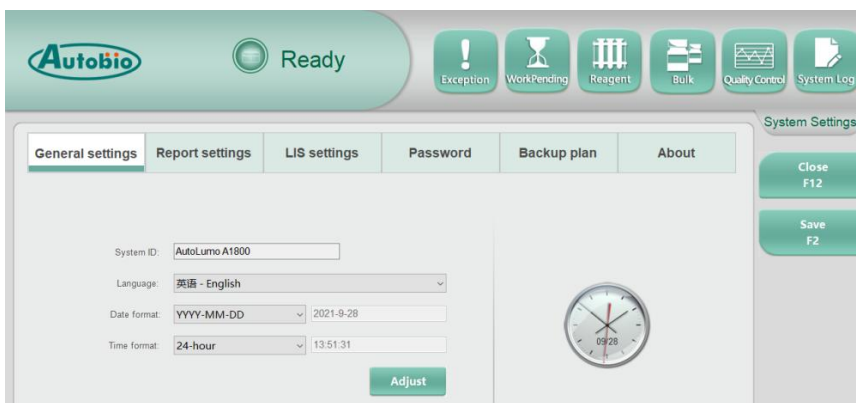
### 4.1.5.2 System Parameter Setting

Click the “System Setting” button on the main interface of the system software to enter the “System Setting” interface. Users with different permissions can set different contents.

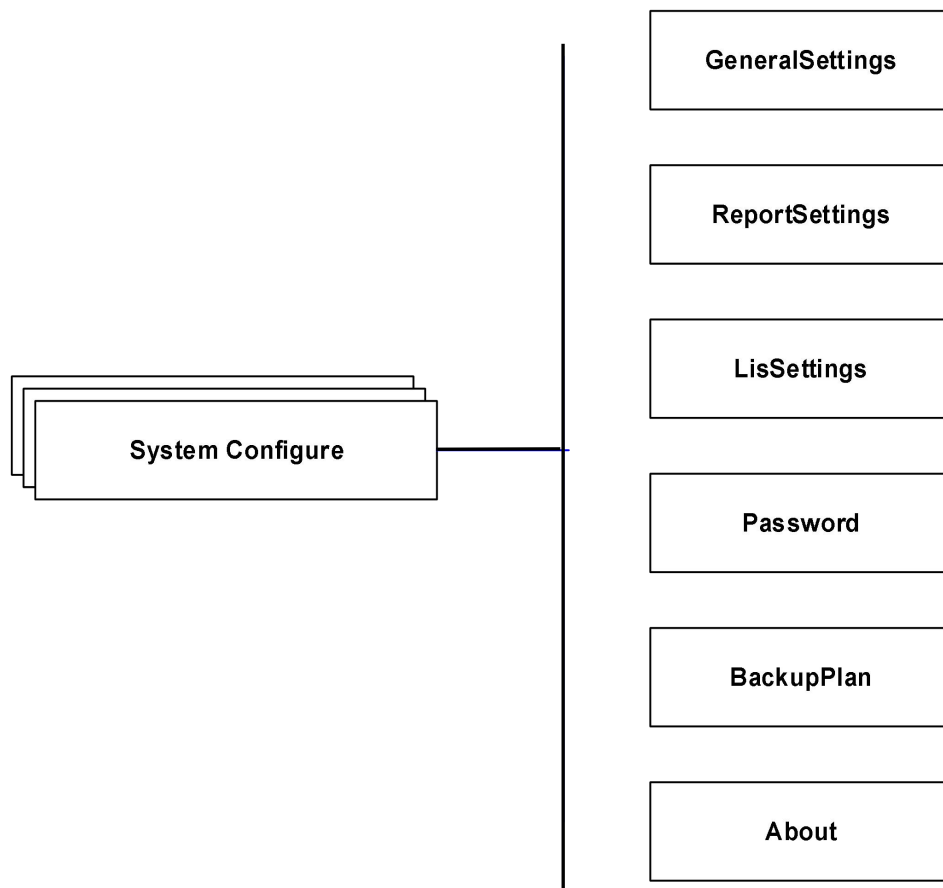
Maintainer rights: including basic software settings, report information settings, LIS connection settings, alarm settings, hardware configuration and control machine settings, and maintainer password modification.



Administrator rights: including general settings, reporting settings, LIS communications settings, administrator password and backup plan, about.



The menu contents are as follows:

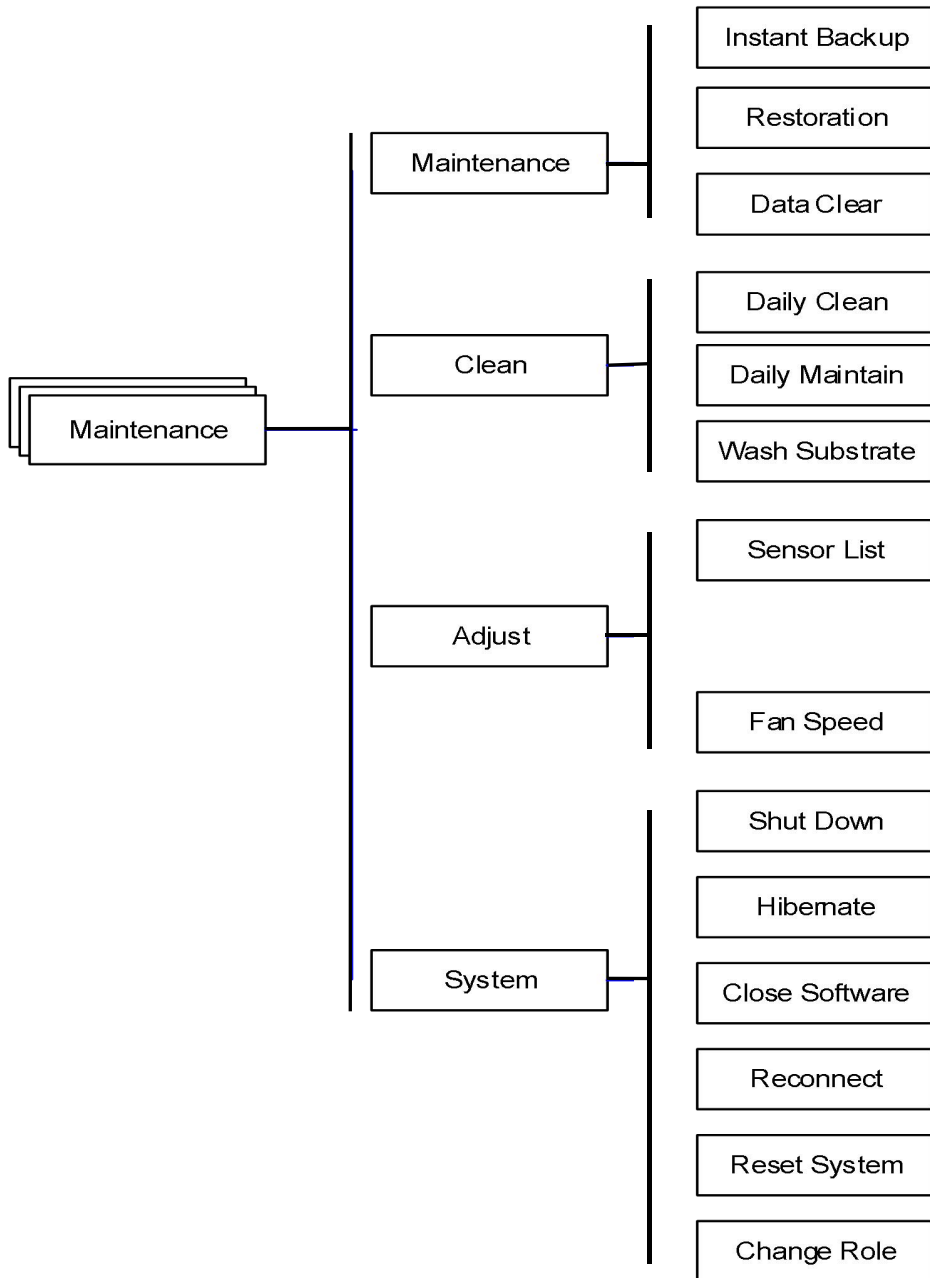


### 4.1.5.3 Maintenance

Click the “Maintenance” button on the main interface of the system software to enter the “Maintenance” interface.

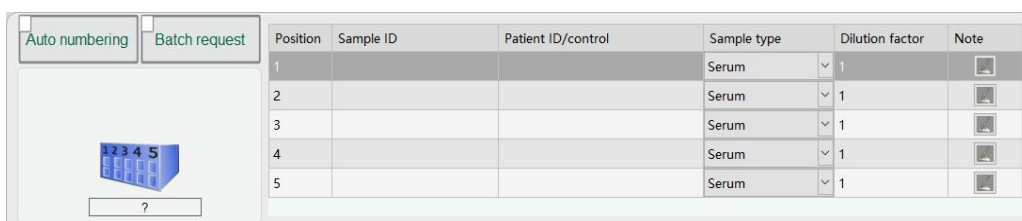
This interface provides the following functions: maintenance, cleaning, commissioning, and system.

The menu contents are as follows:



## 4.2 Patient Sample

Run the software to enter the main menu interface, select “Test and Analysis” to enter the test analysis wizard page interface, select the “Patient Test Request” in the test request, you can enter the patient test request interface to manage the patient test samples.



Interface description

Name	Description
Sample rack No.	Use the mouse to click ? (see location RD02 above) to activate the sample rack input box.
Location	Fixed autonumber from 1 to 5.
Sample No.	Sample bar code or number.
Medical record No/quality control	Medical record number of sample or name of QC.
Sample type	At present, the samples supported by the instrument include serum, urine and plasma. If you need to test other samples, please contact the manufacturer or agent to confirm your operation.
Dilution outside the instrument	The default multiple is 1. Please select according to the actual dilution factor of the sample before the experiment. The instrument will automatically calculate the test result.
Note	Add sample notes.
Automatic numbering	After this function is enabled, the number of the next sample can be automatically generated when the patient test samples are entered (increasing successively without manual input).
Batch request	After this function is enabled, the test request that replicates the last sample generates a new test sample. This feature is designed to facilitate the entry of a large number of samples tested for the same item.
Close this window	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation interface is displayed before entering this screen, the system returns to the main screen.
Delete sample rack	Delete the current sample rack and the sample information



	it contains. If the sample rack number does not exist, the button is unavailable.
Delete sample	Delete the selected sample and its detection request information. If the sample does not exist, the button is unavailable.
Calibration request	Switch to the calibration test sample management interface.
Quality request	Add quality control test sample button.
Obtain LIS request	The online information button is unavailable if the sample does not exist or if the sample is not a patient sample
Sample information	Displays the selected sample information button. If the sample does not exist, the button is unavailable.

**CAUTION:**

Each sample rack contains a maximum of 5 samples. After entering the patient test request interface, the information of sample rack and its sample is empty, and the sample information can be displayed only when the sample rack number is re-entered. If the input sample rack number exists, the sample information contained in it will be displayed on the interface accordingly. If the input sample rack number does not exist, it will be added as a new sample rack, and the sample information needs to be added again.

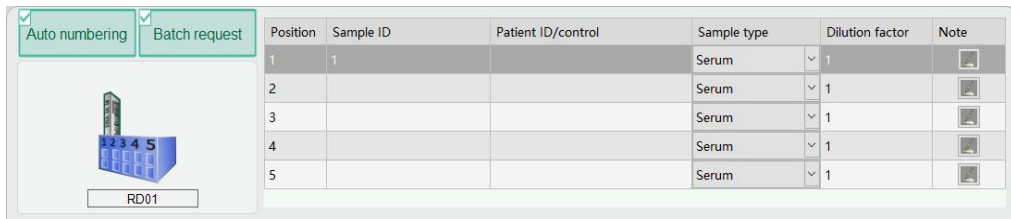
Emergency function: If the sample needs to be tested first, please put the sample in the emergency room after editing, and the instrument will test the sample first.

### 4.2.1 Add Sample Rack and Sample

1) The sample rack cannot be put into the sample tray when the button/indicator of the sample tray is on, you need to wait until the light is off to open the middle door, and then click the "sample tray turntable button". The sample tray will rotate. When the sample tray is rotated to a vacancy and the indicator light of the sample rack is green, the sample rack can be put into the slot, and then the middle door can be closed. The sample tray does not work without the cover.

2) Click "Box Position" on the software interface to activate the sample rack input box.

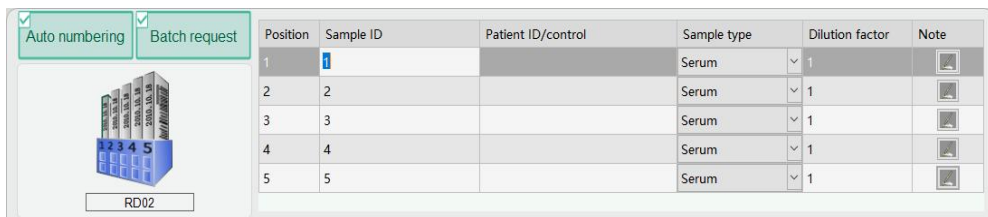
3) After entering the sample rack number "RD01" in the input box, you can input the sample number in the sample information bar or scan the bar code through the scanning instrument as the sample rack number.



4 ) After entering the sample number 1 (which can be distinguished by other numbers), you can enter the medical record number, set the sample type, the dilution multiple outside the instrument, whether there is a note and other information, and enter the medical record number/quality control product name first.

5 ) Set the sample type: such as serum.

6 ) Set the dilution factor outside the instrument as required.



7 ) Add notes. Click the note button and the note information box will pop up. Enter the note information in the information box and click the submit button to add notes to the sample. So far, the sample rack and its sample information are entered into the database.

8) Add the corresponding sample to the corresponding position of the instrument sample rack, that is, the sample rack and its samples are added.



1) Before the test is started, the sample rack and its sample information can be entered first, or samples can be added to the instrument sample rack before the information is entered, and the test results will not be affected; If a sample is added during the testing process, it is necessary to input the sample rack and its sample information first, and add samples to the instrument sample rack. Otherwise, the system will not recognize the newly added samples after the testing begins, and the sample rack will be directly pushed out, and the test cannot be carried out.

2) The input bar code on the sample rack must be consistent with the actual bar code on the sample rack.

3) In order to ensure the reliability of test results, please determine the amount of remaining samples before starting the experiment, and ensure that the amount of remaining samples is greater than or equal to 150ul (dead volume of sample cup) + the amount of samples

required for the actual test.

4) When placing the edited sample rack into the loading position of the instrument sample rack, please confirm that the resetting of the large push hand for sample loading is complete before placing the sample rack.

#### NOTE:

1) The sample rack number consists of the identification number and the serial number. It can be two or four digits. If it is two digits, it must be numbers and the input range is 01-99. If the value is four digits, the first two characters must be uppercase letters and the last two characters must be numbers with the input range 01-99.

2) To enter the sample information, the sample number must be entered first; otherwise, the sample information cannot be entered; Sample information should be selected and filled in according to user's needs.

3) The sample number and medical record number can only be letters (A-Z) or numbers (0-9).

## 4.2.2 Edit Patient Information

After adding the sample rack and its sample information, the following methods can be used to edit the patient information:

- 1) Select the sample whose patient information is to be edited, click the sample information button, and the patient information box will pop up;
- 2) Edit the information of patients;
- 3) After clicking OK, the new edited information is saved. Click the sample information button again, and the patient information will pop up as the edited and saved information.

**Patient info**

Patient info

Patient ID:

Name:  Surname:

Gender:  Male  Female Age:

Department:  Ward:

Bed No.:  Doctor:

Date:  Operator:

### 4.2.3 Input Test Request

- 1) Select a test request for the current sample and one or more tests may be performed for each sample.
- 2) Select the sample to which the detection request is to be added;
- 3) Add the request to be tested in the standard test or combination test selection box and set the dilution factor.

### 4.2.4 Delete Sample Rack and Sample

- 1) Delete samples
  - a) Enter the sample rack number to be deleted in the sample rack number input box;
  - b) Select the sample to be deleted;
  - c) Click the “Delete Sample” button on the right side of the interface;
  - d) After “OK” is selected, the sample and the test request information it contains will be deleted, and the corresponding sample will be removed from the sample rack.
- 2) Delete the sample rack
  - a) Enter the number of the sample rack to be deleted;
  - b) Click the “Delete Sample rack” button on the right side of the interface;
  - c) After clicking “OK”, the sample rack and the sample information contained therein will be deleted;

If necessary, remove the corresponding sample rack from the instrument.

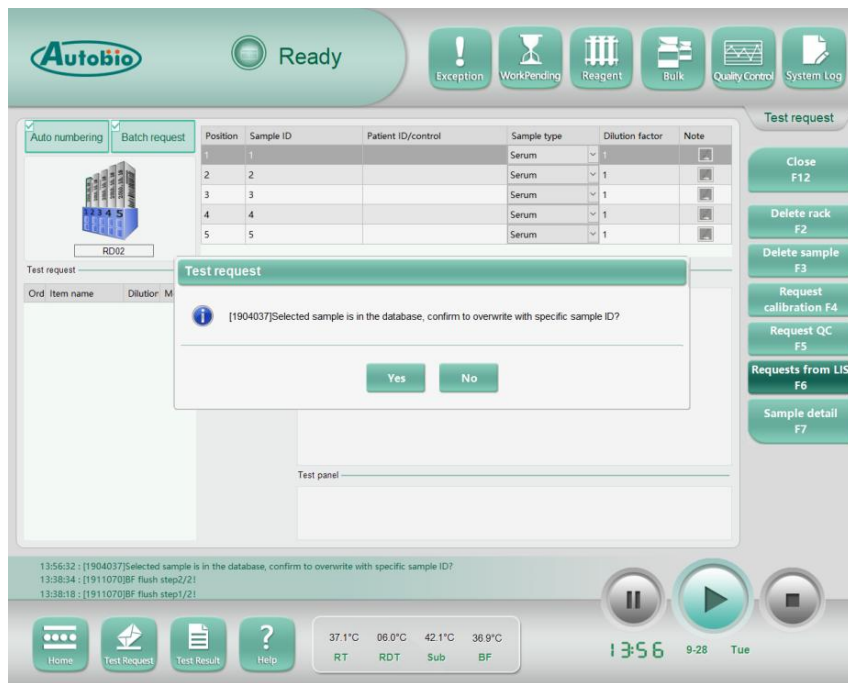


#### **CAUTION:**

The software will not be able to edit, move or remove samples that have entered the sampling line.

### 4.2.5 Obtain LIS Request

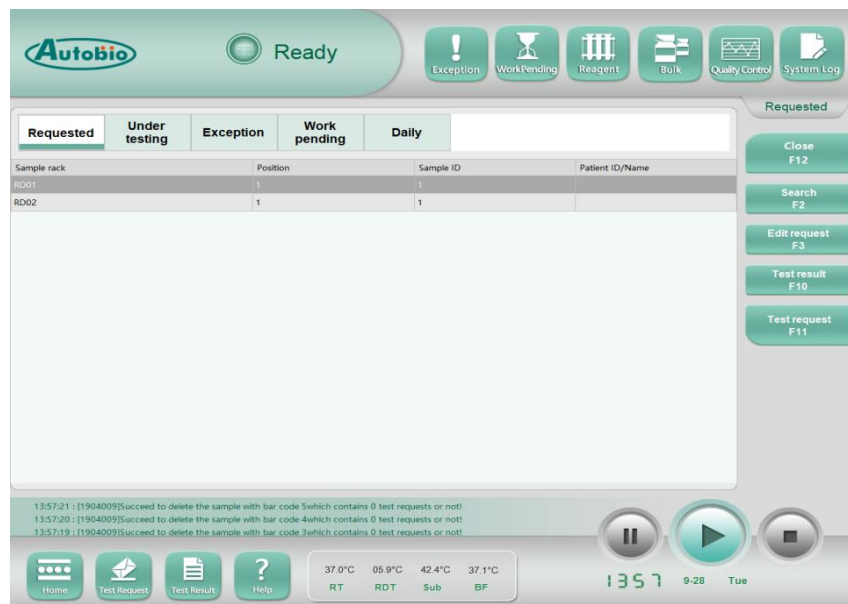
- 1) Add a sample rack;
- 2) Select the placement position of samples on the sample rack;
- 3) Input the sample number;
- 4) Select the “Obtain LIS request” button;
- 5) After clicking “Yes”, the sample rack and its sample information will be overwritten.



## 4.3 Sample Management

### 4.3.1 Request Queue

On the main interface, select Analyse test. On the Analyse test wizard page, select Request Queue. The Request Queue window displays information about samples for which detection requests have been made but which have not yet entered the sampling line.



## Window description

Button name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface.
Search	Finds a sample with the specified sample number
Edit request	Switch to the interface corresponding to the selected sample type to edit the detection request for the selected sample
Test result	Switch to the test results management interface
Test request	Switch to the test request page

### 1) Find samples

Click the “Search” button to switch to the “Find samples by sample number” dialog box, and enter the sample number to find.

### 2) Edit the test request

Select the sample to be edited and click the Edit Request button to switch to the “Test Request” window to edit the selected sample.

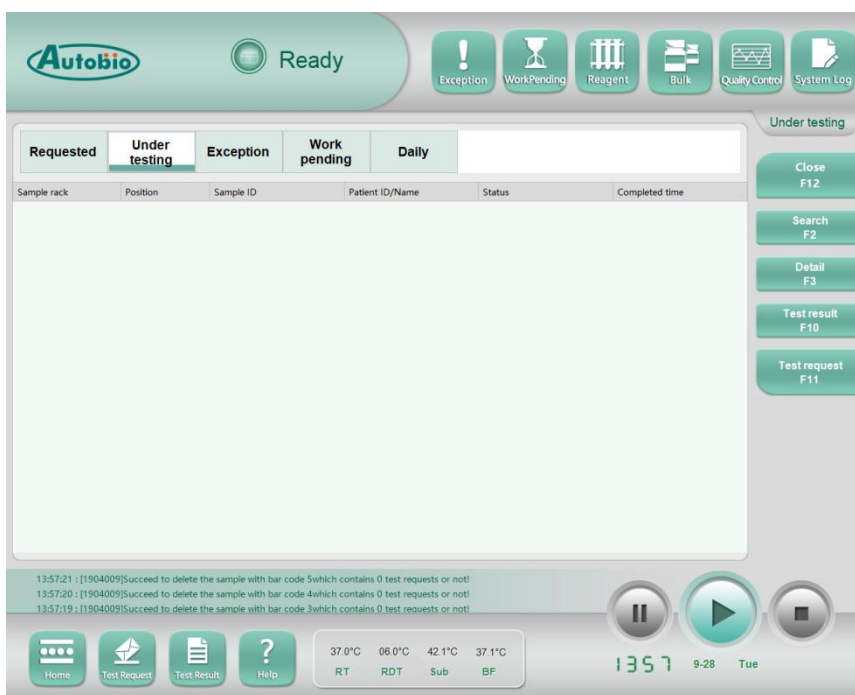


#### **CAUTION:**

The user cannot change the number of the sample rack and the location of the sample. If necessary, please delete it and enter it again.

## 4.3.2 Running Queue

On the menu of the main interface, select Analyse test to enter the Analyse test-Wizard page. Select “Queue”. The “Queue” window displays the information about the samples currently being tested.



### Window description

Button name	Description
Close this window	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface
Search	Finds a sample with the specified sample number
Detail	Display the progress of the samples being tested on the instrument
Test results	Switch to the test result management page
Test request	Switch to the detection request management interface corresponding to the selected sample type

#### 1) Find samples

Click the “Search” button to switch to the “Find samples by sample number” dialog box, and enter the sample number to find.

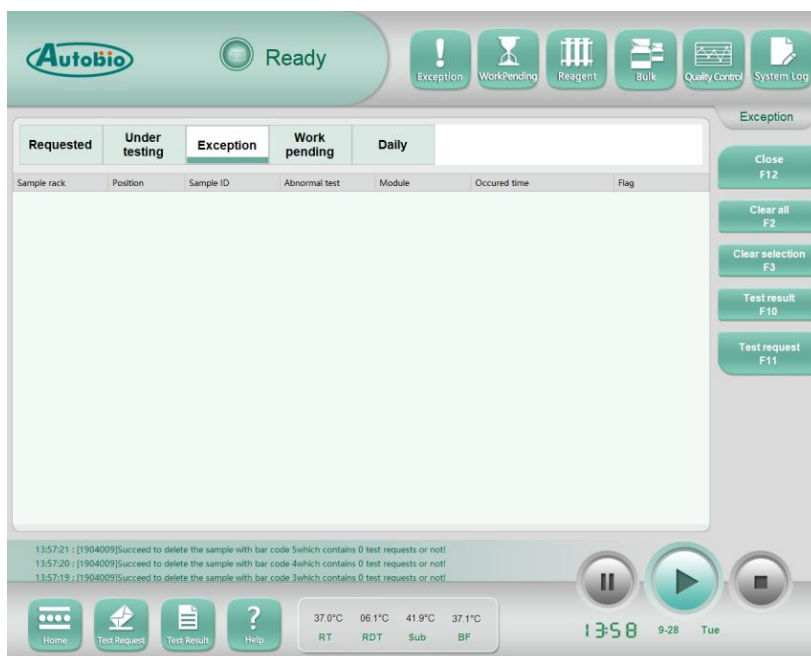
#### 2) Viewing details

Select the sample whose details you want to view and click the details button to view the

details of the selected sample. The details window displays the test name, completion time, status (including sampling, dilution, reagent addition, etc.), marking, and speed of operation in the instrument for the selected sample.

### 4.3.3 Exception

On the main interface menu, select Analyse test to enter the Analyse test-wizard page. Click exception, and the detection request information of all detected exceptions is displayed in the window.



#### Window description

Button name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface
Clear all	Clear all abnormal samples displayed on the page
Clear selection	Clear the information about the selected abnormal samples
Test result	Switch to the test results management interface
Test request	Switch to the test request management interface corresponding to the selected sample type



Clear all detected abnormal samples information

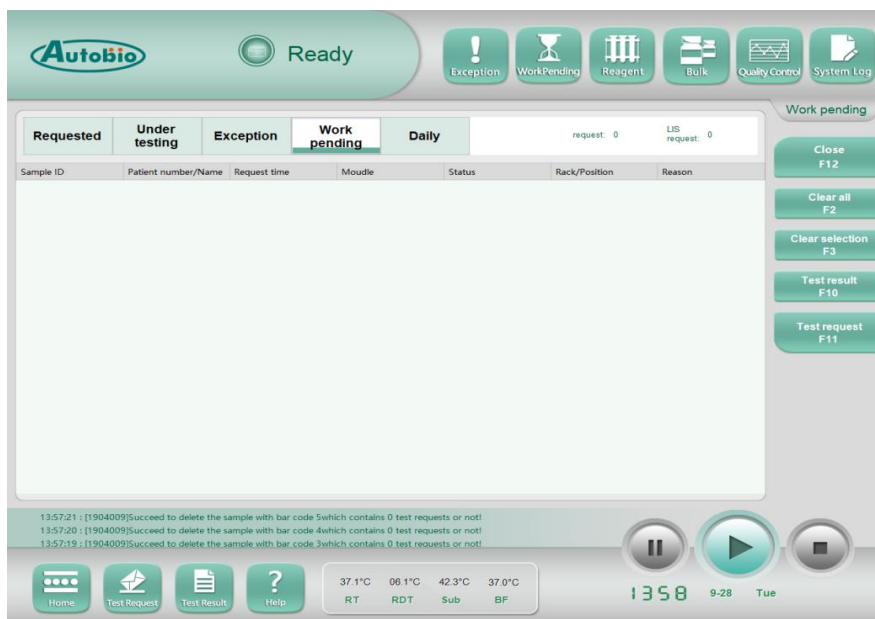
- 1) Click the Clear All button on the interface, and all abnormal sample information on the interface will be cleared;
- 2) Clear the information of selected samples with abnormal detection;
- 3) Select the sample information to be cleared and click the Clear button on the interface. The currently selected abnormal sample information will be cleared.

**NOTE:**

- 1) Abnormal information includes “Sample Rack”, “Location”, “Sample Number”, “Abnormal Detection”, “Occurrence Time” and “Mark”.
- 2) For abnormal reasons, refer to the appendix flag.

### 4.3.4 Work Pending

On the main interface menu, select Analyse test to enter the Analyse test-wizard interface. Select “Work Pending” button. The test request information in the work pending window is displayed.



Window description

Button name	Description
-------------	-------------

Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface
Clear all	Deletes all work waits currently displayed, including previous and current edits
Clear selection	Delete the selected work waiting sample, select the work waiting sample to be deleted, click the delete button on the interface, and the information of the currently selected work waiting sample will be deleted
Test result	Switch to the test results management interface
Test request	Switch to the detection request management interface corresponding to the selected sample type

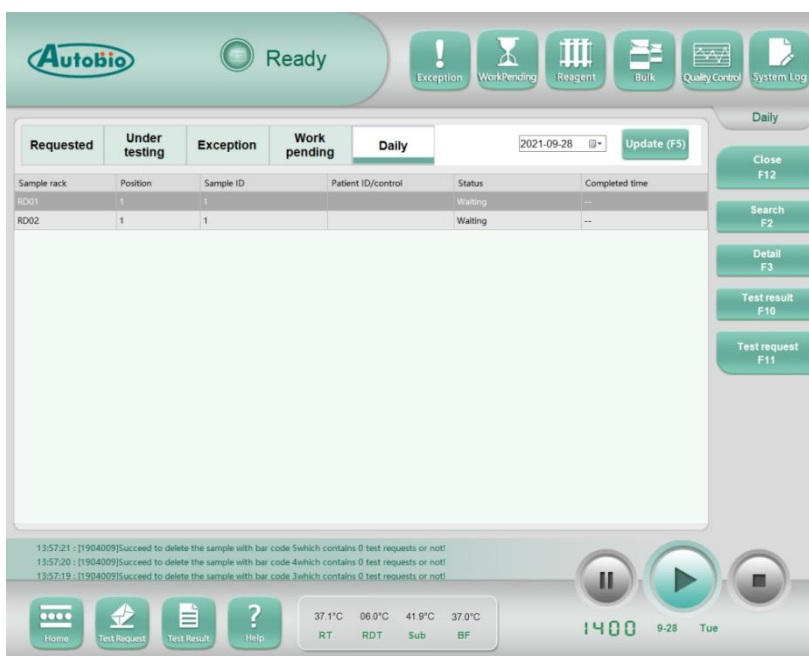


**NOTE:**

- 1) The work pending shows the abnormal samples in the test. Reasons include “CLT (sample blocking probe)”, “QNS (insufficient sample size)”, “QNR (insufficient reagent)” and “No Test”.
- 2) If there is a work pending test, the work wait button on the main interface flashes and displays yellow.
- 3) If you need to edit the sample rack again, you need to clear the waiting sample rack.

### 4.3.5 Daily Samples

In the main interface menu, select Analyse test to enter the Analyse test-Wizard interface. Select “Daily Sample” button to switch to the daily sample window, which displays all sample information of the specified date.



Window description

Button name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface
Search	Find the sample with the specified sample number, click the “Search” button to pop up the “Find samples by sample number” dialog box. Enter the sample number you want to find.
Detail	Display detailed information of all samples on the day (including sample rack, location, sample number, medical record number/name, status, completion time)
Test result	Switch to the test results management interface
Test request	Switch to the detection request management interface corresponding to the selected sample type

**NOTE:**

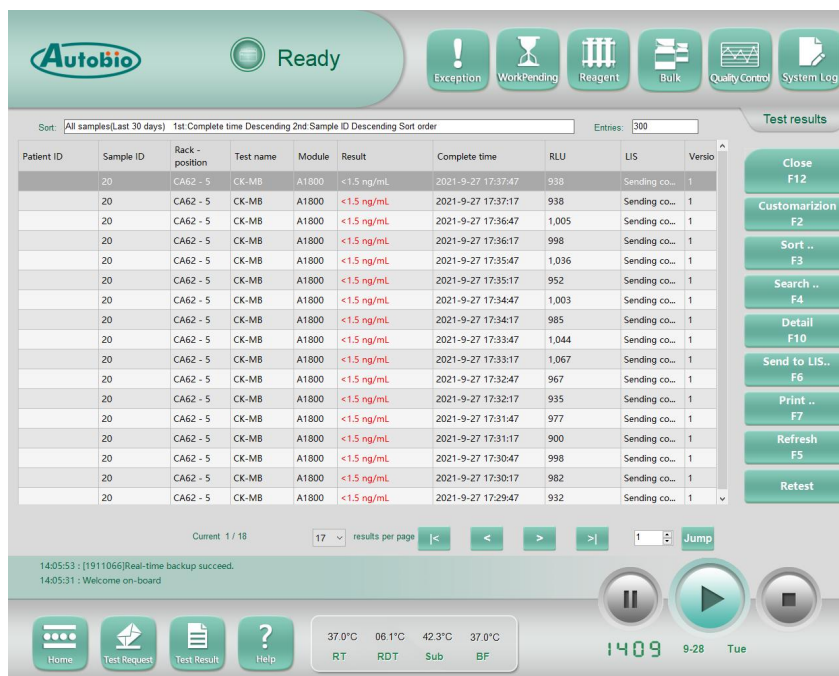
Sample state.

Complete, queuing, abnormal.

Completion time is the estimated time to complete all tests. If the current completion time cannot be estimated, "--" is displayed.

## 4.4 Test Result

In the main interface menu, select Analyse test to enter Analyse test - Wizard interface - Result Analysis. According to the test result data you need to display, select the corresponding button.



### Window description

Button name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface
Customization	Select the display items of test results and customize the display sequence
Sort	Establish screening conditions and screening test results data
Search	Finds records for the specified criteria in the filtered test results
Detail	Displays the detailed information contained in the test

Sent to the LIS	Send test results to LIS system
Print	Prints test result data
Refresh	Refresh current test result
Retest	Test again

#### 4.4.1 Customizing Display Items

For the test result, the user can set the item information to be displayed under their requirements. Click the customization button, select the item to be displayed and the display order in the pop-up box, and click OK to display the detection result according to the customized settings.

#### 4.4.2 Screening Test Results

Click the Screening button to enter the screening condition setting interface. You can select the existing screening conditions or establish new screening conditions. After setting the screening conditions, click OK to screen the test results according to the set conditions.

#### 4.4.3 Find Test Results

Click the Find button after screening the test results according to the screening conditions, and click Find button after setting the find conditions to find the test results.

#### 4.4.4 Viewing Detailed Information

Select the test result whose detailed information you want to view and click the detailed information button to view the detailed information of the selected detection result in the pop-up detailed information window.

#### 4.4.5 Send Test Result to LIS System

Select the test to be sent and click the "Send to LIS system" button to send the test result to the LIS system.

#### 4.4.6 Print Test Result

The test results can be printed out in the form of reports. Click the print button to print the test results into reports. Refer to the report description section for the report format.

#### 4.4.7 Refresh Test Result

Test results can be updated to the latest status, click the refresh button to update.

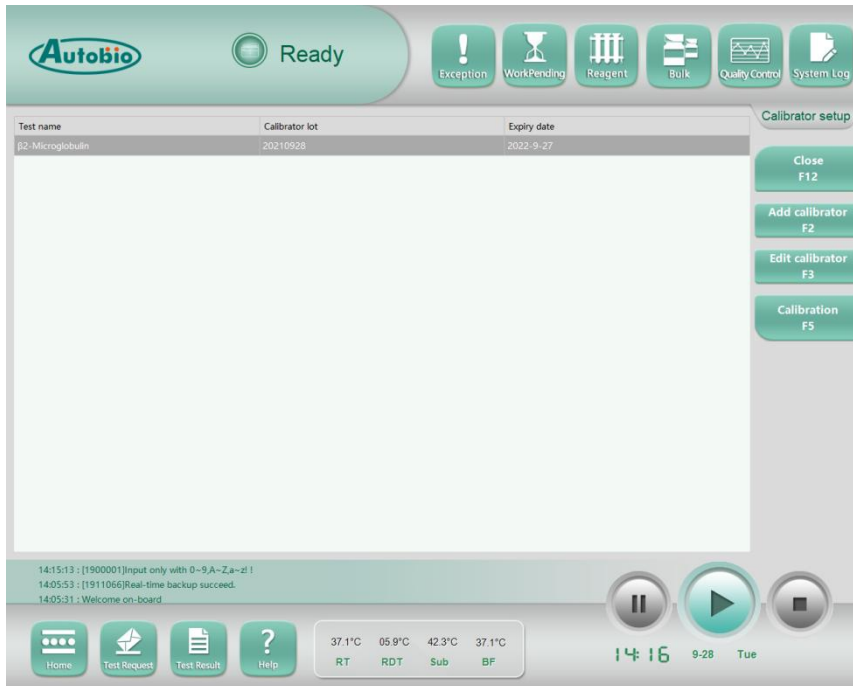
#### 4.4.8 Retest

You can retest the selected tests by selecting one or more tests.

## 4.5 Calibration

### 4.5.1 Calibrator

On the main interface menu, select Analyse test to enter the Analyse test-Wizard interface, and select calibrator setting to enter the calibrator setting interface.



#### Window description

Button name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface.
Add calibrator	Click and the add new calibrator dialog box will pop up.
Edit calibrator	Click and the dialog box for editing the selected calibrator will pop up. If the calibrator is not selected, the button is unavailable.
Calibration	Switch to the interface for viewing calibration results.

#### 4.5.1.1 Add Calibrator

**Calibrator editing**

Barcode:

Calibrator:

Lot:

Calibrator:

Expiry date:

Test name	Calibrator	Theoretical Concentration	Unit
-----------	------------	---------------------------	------

OK Cancel

- 1) Click the add calibrator button to switch to the add new calibration solution dialog box;
- 2) Scan or input the bar code of the calibrator;
- 3) Scan or input the bar code of each calibrator;
- 4) Select OK button.

#### 4.5.1.2 Edit Calibrator

**Calibrator editing**

Barcode:

Calibrator:

Lot:

Calibrator:

Expiry date:

Test name	Calibrator	Theoretical Concentration	Unit
β2-Micro...	S0	0	μg/L
β2-Micro...	S1	50	μg/L
β2-Micro...	S2	150	μg/L
β2-Micro...	S3	400	μg/L
β2-Micro...	S4	1000	μg/L
β2-Micro...	S5	4000	μg/L

OK Cancel

- 1) Select the calibrator to be edited and click the edit calibrator button to switch to the edit calibrator dialog box;

- 2) Scan or input the bar code of calibrator;
- 3) Select OK button.

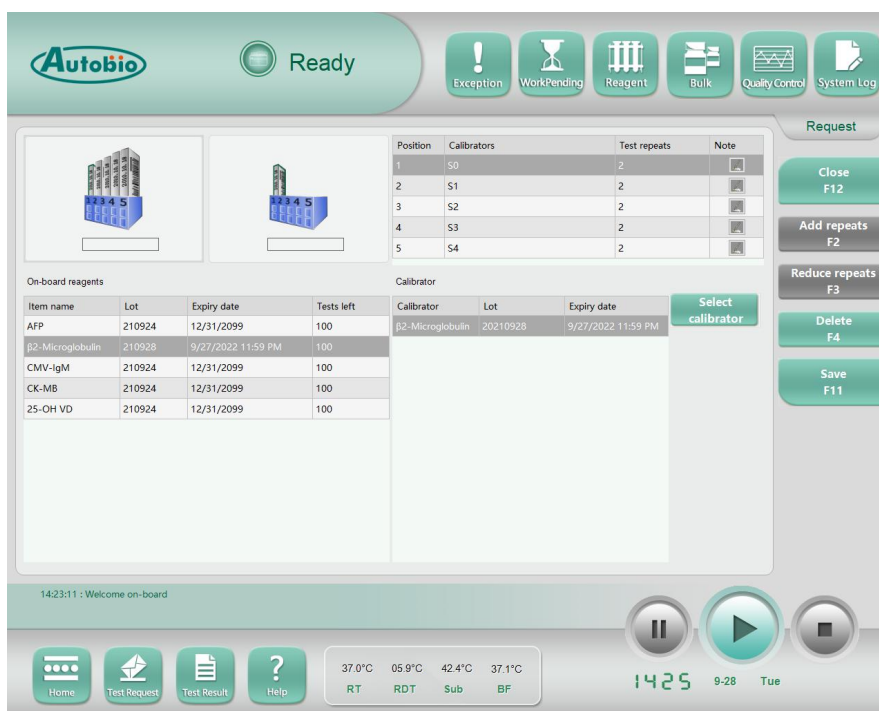
## 4.5.2 Calibration Tests

### 4.5.2.1 Enter Calibration Request Interface

On the main interface menu, select Analyse test to enter the Analyse test-wizard interface, and select calibration detection request to enter the calibration request interface.

#### NOTE:

- 1) Each sample rack contains a maximum of 5 samples, and a set of calibration test request contains 2 to 7 calibrators, so calibration test may need to add two sample racks.
- 2) In the selection of calibrator, only the calibrator of the same batch as the corresponding reagent is allowed to be selected.



#### Window description

Name	Description
Sample rack no.	Use the mouse to click ?, and the sample rack input box can be activated.
Location	Fixed autonumber from 1 to 5.



Calibrator	Calibration names are marked S0 to S6.
Test times	The test times can be modified. The number of qualitative tests is 1-3 times, and the number of tests of each calibrator can be set separately; The number of quantitative detection is 1-2 times, and the number of detection of each calibration must be equal; The default test times for both qualitative and quantitative testing are 2 times.
Note	Add sample notes
Item name	Distinguish the individual items
Batch number	Date of production of the reagent
Period of validity	The expiration date of the reagent
Remaining times	The number of remaining uses of the reagent
Close this window	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this screen, the system returns to the main interface
Increase the number	Click the button once to increase the number of tests of the currently selected calibrator by 1
Reduce the number	Click the button once to reduce the number of tests of the currently selected calibrator by 1
Select calibrator	Adds calibration information for the currently selected item to the sample rack
Delete	Delete the current sample rack and the sample information it contains. If the sample rack number does not exist, the button is unavailable
Save	Save the information of the added calibration to the system, and the new calibrator must be saved before testing

#### 4.5.2.2 Add Sample Rack and Calibrator

- 1) Dispense each calibrator used for this calibration into the reaction container;
- 2) Put each calibration product containers according to the serial number into the sample rack;
- 3) Select the calibrator used in this calibration in the calibrator list box;

4) Select the “Select Calibrator” button;

Scan or enter the bar code of the sample rack used for this calibration.

### 4.5.2.3 Edit the Calibration Request

1) Scan or input the first sample rack bar code of the calibration request to be edited in the bar code box of the sample rack;

2) Select the kit to be used from the kit list box on the instrument;

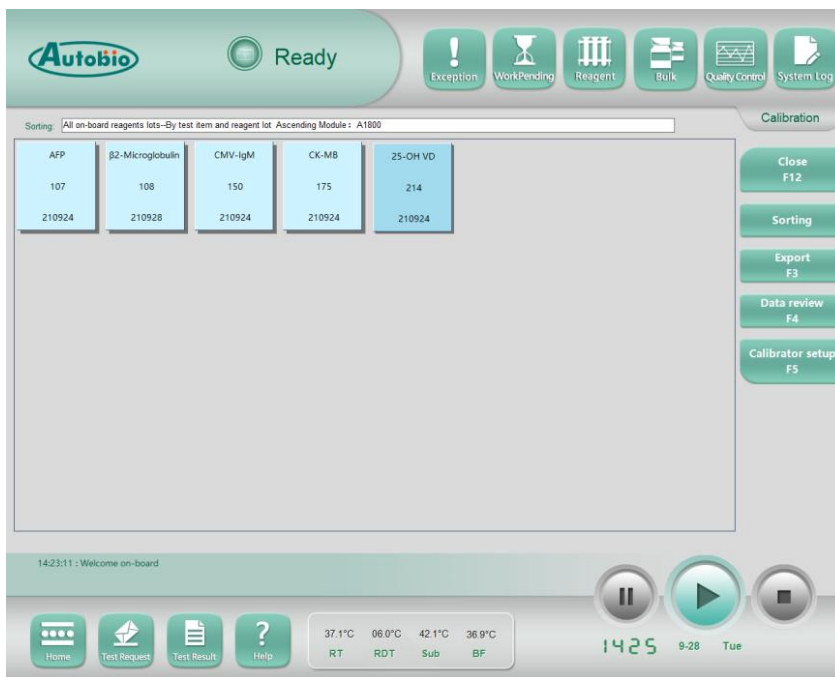
3) Select the calibrator used in this calibration in the calibrator list box;

4) Select the “Select Calibrator” button;

Scan or enter the bar code of the sample rack used for this calibration.

### 4.5.3 Calibration Results

On the main interface menu, select Analyse test to enter the Analyse test-Wizard interface. Click “Calibration” to switch to the calibration management window to view the calibration result data generated after the detection.

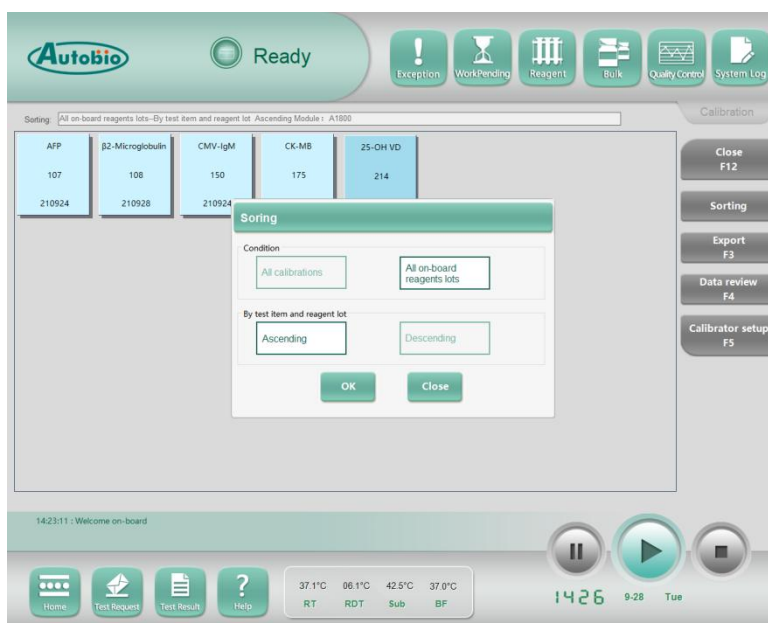


#### Window description

Name	Description
Close this window	Exiting this Interface

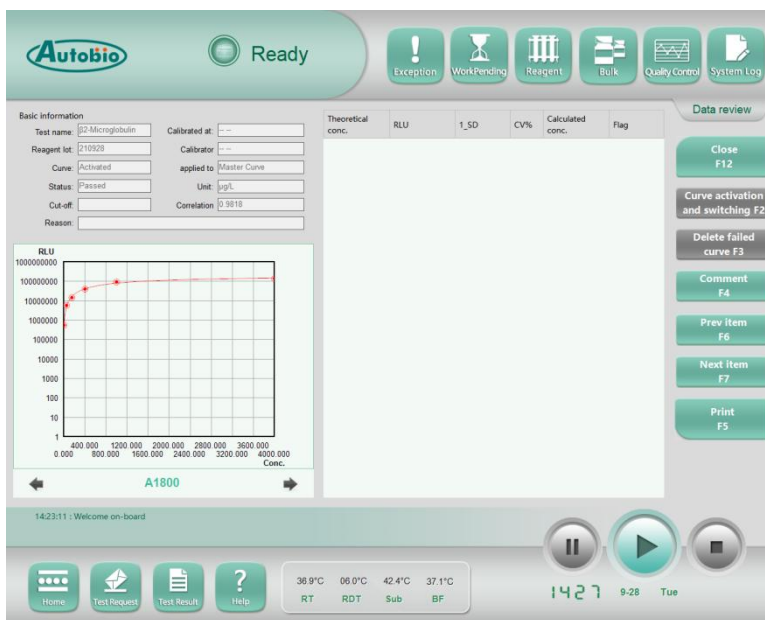
Screening	The calibration results are screened and managed according to the set conditions
Data review	View the test data and calibration curve contained in the selected calibration results
Calibrator setting	Enter related settings interface

### 4.5.3.1 Screening Calibration Results



- 1) Enter the calibration management interface and click the screening button to pop up the screening condition setting box;
- 2) Select screening conditions;
- 3) Select the sorting mode;
- 4) Select OK button.



### 4.5.3.2 Review Data



Select the calibration of the data to be reviewed and click the “Review Data” button to switch to the result data review interface. The data review interface mainly includes calibration basic information, calibration data and calibration curve.

#### Window description

Name	Description
Calibration basic information	<p>Basic information includes “Test Name”, “Reagent Batch Number”, “Calibration Time”, “Calibration Period”, “Unit”, “Calibration Curve”, “Status”, “Cause”, “Calibration Solution Batch Number” and “Critical Value”.</p> <p>Calibration time is the time when calibration test is completed, and calibration validity period is calibration time plus calibration valid days (this parameter is set in calibration solution).</p> <p>Calibration curve includes “Active” and “Inactive”</p> <p>4. The status can be Passed or Failed.</p> <p>5. The cause information includes RLU exceeds the limit; “Insufficient Data”; “HCV”, Bad Fit, Not Fit.</p>
Calibration data	<p>Calibration result data includes “Specified Concentration”, “RLU”, “1_SD”, “CV%”, “Calculated Concentration” and “Flag”</p> <p>The branch shows the test result value of the calibration product tested twice and the average value of the specified concentration of the two values, the average value of the calculated concentration, 1_SD, CV%;</p> <p>“No Value” is displayed if there is no data for concentration calculation.</p>

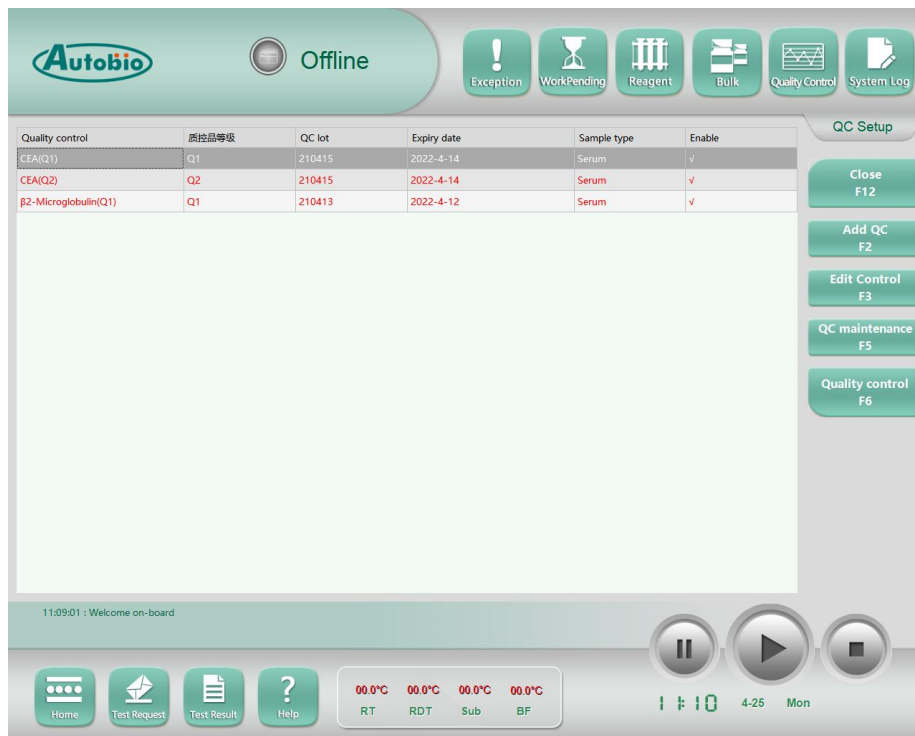
Calibration curve	<p>The curve was drawn according to the calibration concentration and the RLU value. Qualitative items have no calibration curve.</p> <p>The X axis represents the concentration value and the Y axis represents the RLU value.</p> <p>The minimum and maximum values of the X-axis are equal to the minimum and maximum values of the calibrator.</p> <p>The maximum and maximum values of the Y-axis are calibrated according to the parameter table of the test items.</p> <p>The calibration curve is drawn according to the fitting curve of the item.</p> <p>Qualitative items have no calibration curve, showing “No Graph”.</p>
Close	Exit this interface, return calibration management interface
Convert activation and switching	Select the current calibration curve as the active calibration curve
Delete the curves that failed validation	Delete calibration curves that fail validation
Note	Add a comment to the currently displayed calibration curve
Print	Print the current calibration results (calibration basic information, calibration data, calibration curve)
	Switch to the previous curve
	Switch to the next curve

## 4.6 Quality control

Quality control is an important means to verify whether the overall performance of the instrument is effective. When the instrument has been used for a period of time, errors occur because of machine wear or some other factor. Analyze the validity of instrument test results through quality control test results.

### 4.6.1 Quality Control Product

In the main interface menu, select Detection and Analysis to enter the Detection and Analysis-Wizard interface. Select Quality Control Product Settings in Quality Control to enter the Quality Control Product Settings interface to manage and set quality control products.



### Window description

Name	Description
Close	Exiting this Interface
Add QC	Add new quality control products to the system
Edit QC	Edit the current selected quality control data
QC maintenance	Establish the mean value (target value), SD, test items and other basic data of quality control products
QC	Enter quality control interface

#### 4.6.1.1 Add Quality Control Product

Test name	Mean	SD	Unit	Method	1-2S	1-3S	2-2S	R4S	3-1S	4-1S	7T	7X	10X

- 1) Enter the QC setting interface and select the “Add Quality Control Product” button to switch to the “Add Quality Control Product Information” dialog box;
- 2) If you need to add quality control products that are not produced by Autobio, please enter the quality control product number, quality control product name, batch number, and validity period established in the quality control product maintenance window.
- 3) If you need to add quality control products produced by Autobio, please enter the corresponding bar code of quality control products;
- 4) Select the quality control rules for the test items included in the quality control product;
- 5) Select “OK” button.

#### NOTE:

Rule of QC loss:

- 1) 1 quality control point falls outside  $\pm 2s$ : 1-2s. (1-2s: It is warning rule, other QC rule can be launched to check the QC data, it is not QC loss rule.)
- 2) 1 quality control point falls outside  $\pm 3s$ : 1-3s. (1-3s: If the QC result not only exceeds  $\pm 2s$  but also exceeds  $\pm 3s$ , it will be judged as QC loss. The rule prompts of system error).
- 3) 2 consecutive quality control points fall into the same side  $\pm 2s$ : 2-2s. (In the same batch, 2 levels of quality control results exceed + 2S or -2s in the same direction, or the same quality control results exceed +2s or -2s in the same direction twice in succession. It will be judged as QC loss. The rule prompts of system error ) .
- 4) 4 consecutive quality control points fall into the same side  $\pm 1s$ : 4-1s. (Four consecutive results of the same level quality control product exceed 1s in the same direction or the previous results of two level quality control products exceed 1s in the same direction as this

one, and one of them must exceed +2s or -2s in the same direction. It will be judged as QC loss. The rule prompts of system error.)

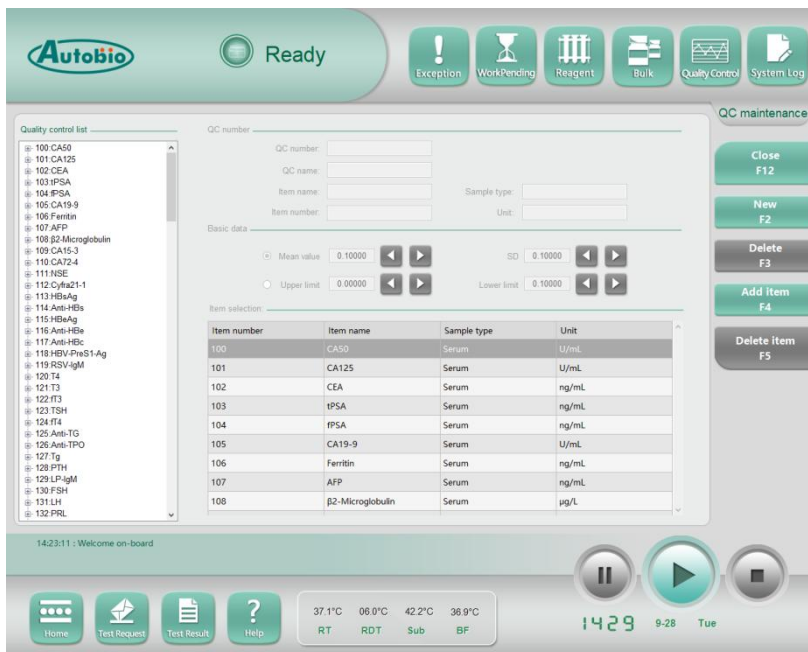
5) 7 consecutive quality control points fall on one side of the mean value; 7x (If there is 1 level quality control with 7 consecutive quality control values on the same side of the mean or 3 level quality control with their quality control values on the same side of the mean for 3 consecutive days, and one of the results must exceed +2s or -2s in the same direction. It will be judged as QC loss. The rule prompts of system error.).

#### 4.6.1.2 Edit Quality Control Product

- 1) Select the quality control product to be edited in the quality control product setting window;
- 2) Select the quality control rules of the test items included in the quality control products;
- 3) Modify the name of quality control product;
- 4) Select OK button.

#### 4.6.2 Quality Control Maintenance

Click the quality control maintenance button on the quality control setting interface to switch to the quality control maintenance interface, where you can maintain third-party quality control products with the permission of the administrator.



#### Window description

Name	Description
------	-------------



Close	Exit this interface and return to the quality control settings interface
New	Establish new quality control products
Delete	Delete the selected quality control product and the test items it contains
Add item	Add the selected test item to the current quality control product
Delete item	Delete the selected test items of the current quality control product

#### 4.6.2.1 New quality control product

- 1) Enter the quality control product maintenance interface and click “New Quality Control Product”;
- 2) Input the quality control product number and name;
- 3) Select new quality control products including the first project “??”;
- 4) Select the corresponding item from the item list;
- 5) Input mean value and SD;
- 6) If the quality control product contains more items, please select the “Add Item” button;
- 7) Repeat steps 4 and 5;

If you need to add more quality control products, repeat steps 1 to 7.

#### NOTE:

- 1) The quality control number shall be three digits ranging from 100 to 999;
- 2) The number of quality control products should not be repeated;
- 3) The quality control product number and name cannot be empty;
- 4) The quality control product shall contain at least one quality control test item.

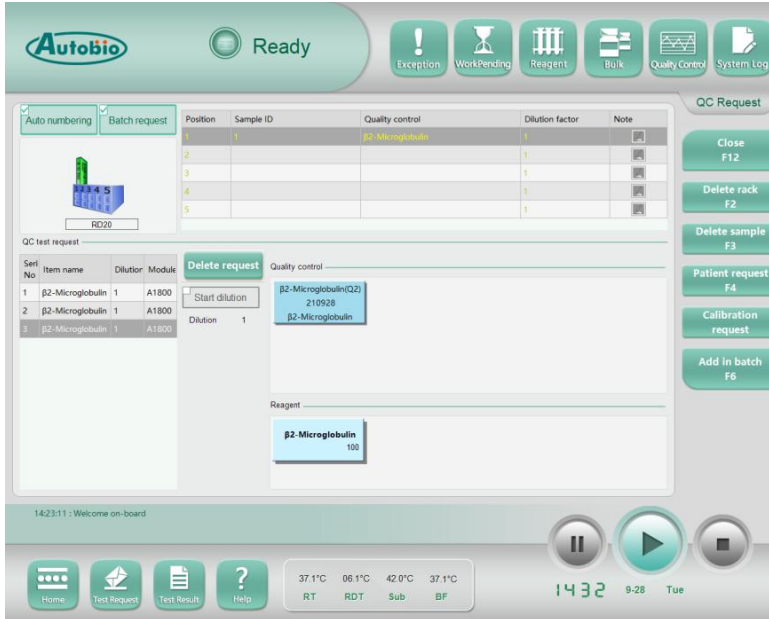
#### 4.6.2.2 Quality Control Request

- 1) The quality control test request adding window is similar to the patient test request adding window, and the sample rack and sample added are the same as the patient test request;
- 2) Add a sample rack;
- 3) According to the placement position of quality control samples in the sample rack, select

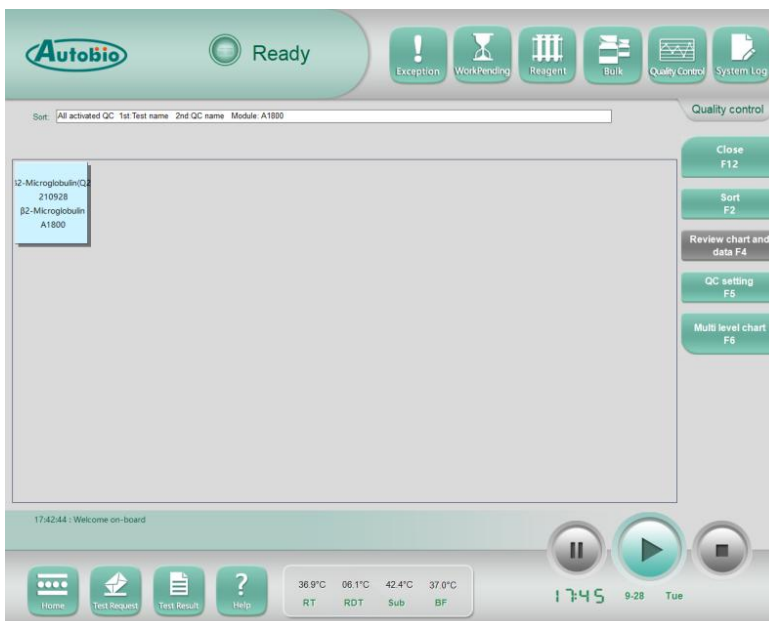
the corresponding position in the sample input list box;

4) Select the quality control product corresponding to the quality control sample in the list on the upper right side, and the quality control product without the corresponding reagent is displayed in red;

5) Select the quality control test items for the quality control sample from the list on the lower right.



### 4.6.3 Quality Control Result



On the main interface menu, select Detection and Analysis to enter the Detection and Analysis-Wizard interface, and click “Quality Control” to switch to the quality control management window to view the quality control result data generated after the quality control test is completed.

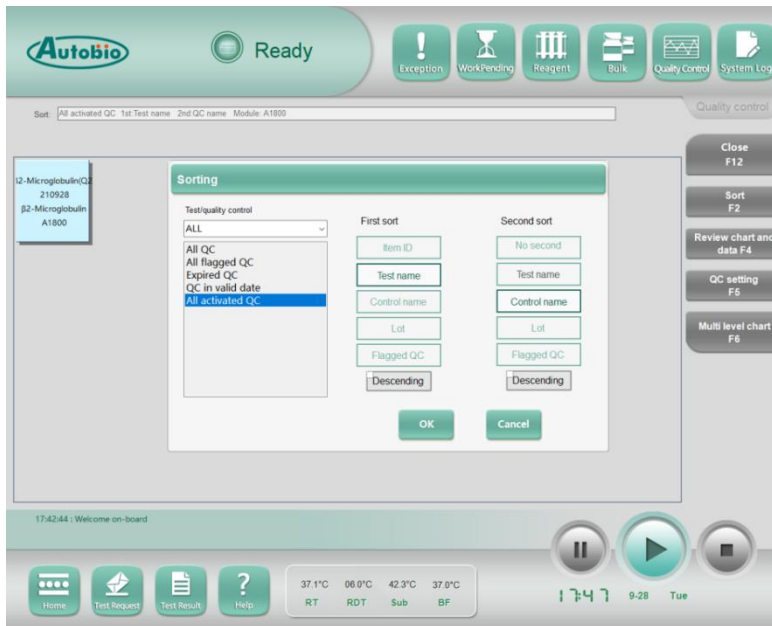
**NOTE:**

When the quality control result is normal, the background color is light blue. If the latest test result of the quality control product is out of control, the background is shown in red.

**Window description**

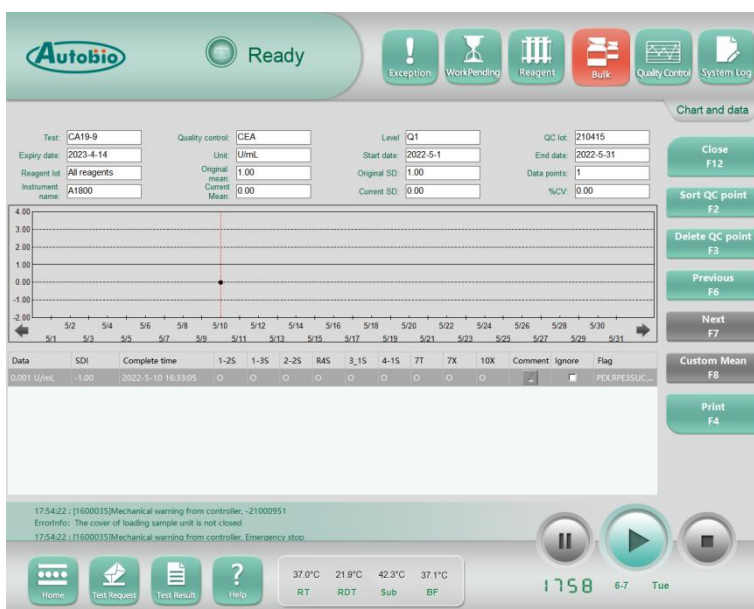
Name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If no secondary navigation screen is displayed before entering this interface, the system returns to the main interface.
Sort	Select and manage the quality control results according to the set conditions.
Review chart and data	View the test result data and quality control chart of selected quality control products. If no quality control result is selected, the button is unavailable.
QC setting	Click to switch directly to the quality control product setting interface.

#### **4.6.3.1 Screening Quality Control Result**





- 1) On the quality control management interface, select screening button to switch to the screening criteria dialog box;
- 2) Select screening conditions;
- 3) Select the sorting mode;
- 4) Select OK button.

#### 4.6.3.2 Review Quality Control Chart and Data



Select the quality control that needs to review the quality control chart and data, and click the review quality control chart and data button to switch to the quality control chart and data review window.

Name	Description
Basic information of quality control product	<p>1. Quality Control Product Basic information: Start Date, End Date, Mean value, SD, %CV, Data Point, Test, Quality Control Product, Quality Control Product Batch Number, Validity Period, Reagent batch Number.</p> <p>2. Mean value means the average of all test results involved in the calculation;</p> <p>SD is the standard deviation calculated from all test result data involved in the calculation;</p> <p>CV is the coefficient of variation calculated from all test results data involved in the calculation;</p> <p>Data points is the number of data records that participate in the calculation.</p>
List of quality control product test data	<p>1. Determine whether the test result data violates the quality control rules according to the set quality control rules. If it violates the quality control rules, mark the violated rules with red font and ** on both sides. For rules of type 2-2S, 1-4S, and 7X, only the last result record that complies with the rule is marked with a violation note.</p> <p>2. The data list only shows the quality control test records with test results; The result tag does not display tags of out-of-range types, with a maximum of two tags.</p> <p>3. The value of qualitative items is S/CO value (measured RLU/ critical value), and other items are concentration values.</p>
Quality control chart	<p>1. Draw Levey-Jennings quality control chart with the test result data of quality control products;</p> <p>2. The Y coordinate displays the detection result value, ranging from -3s to 3S, and the step distance is 1S;</p> <p>3, X coordinate displays date, range from the start date to the end date, step for 1 day, only 31 days on an interface, more than 31 days by moving the left and right button view;</p> <p>4. Draw a horizontal dotted line with a step distance of 1S in the Y-axis direction, and the mean line is a solid line.</p>



Close	Exit this interface, return calibration management interface
Sort QC point	The quality control test results were screened according to the test time range and reagent batch number
Delete QC point	Deletes the currently selected quality control data point
Ignore data points	If a data point is ignored, it will not participate in the calculation of SD and %CV values, and will not participate in the line drawing
Print	Print the current quality control results (basic quality control information, quality control product test data, quality control chart)
	The previous day
	The next day

### Window description

1) Screening quality control points: the quality control test results can be screened according to the detection time range and reagent batch number; The screening criteria can be all, last week, last month, or a specified date (the start date and the last day); Reagent batch number: All, individual reagent batch number.

2) Delete quality control points: If the current user is a common user, the deletion of data points requires the input of the administrator password. If the passwords are consistent, the deletion is allowed.

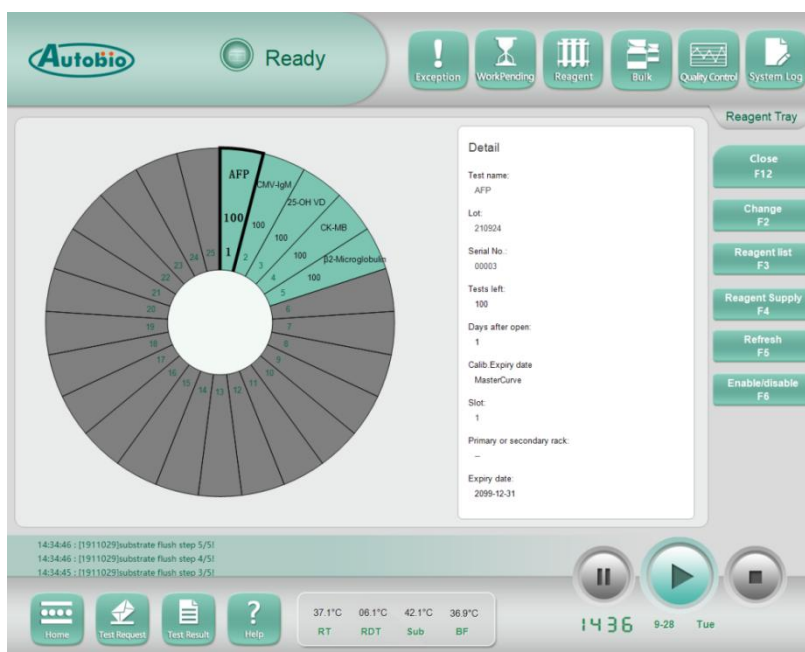
3) Ignore quality control point: this point will no longer participate in the calculation of SD and %CV values, no line drawing.

4) Note of quality control points: notes can be added to the quality control result data; If the data point has been annotated, the note button displays the icon as a text icon ; If no note is added, the note button displays the pen icon .

## 4.7 Consumables

### 4.7.1 Kit

On the main interface menu, select detection and analysis to enter the second-level navigation interface of detection and analysis. Select reagent management to switch to the on-board kit window to view the kit data.



### Window description

Name	Description
Close	Exit this interface and return to the secondary navigation (Detection and Analysis) interface
Change	Perform the kit replacement operation on the instrument
Reagent list	Switch to the Kit list management interface
Reagent alarm	Enter the reagent alarm interface, you can view the status of each reagent
Refresh	Refresh the interface
Enables or disable	Enables or disables the selected reagent

#### 4.7.1.1 Viewing Kit Data

- 1) Select the reagent slot you want to view on the circle chart;
- 2) On the right side of the circle chart, view the kit data installed in the reagent slot you selected.

#### 4.7.1.2 Change Kit

- 1) Open the cover of the reagent tray;
- 2) Press the reagent order button to rotate the reagent tray to the appropriate position and add the kit.
- 3) Close the cover on the reagent tray and press the reagent order button to tell the system that the kit is added.
- 4) Select the change Kit button to switch to the reagent change confirmation" window;
- 5) Check the box of complete kit replacement on the instrument;
- 6) Select the change button;
- 7) After the instrument scanning kit is completed, the change Kit window will be displayed, showing the list of current kits on the instrument.

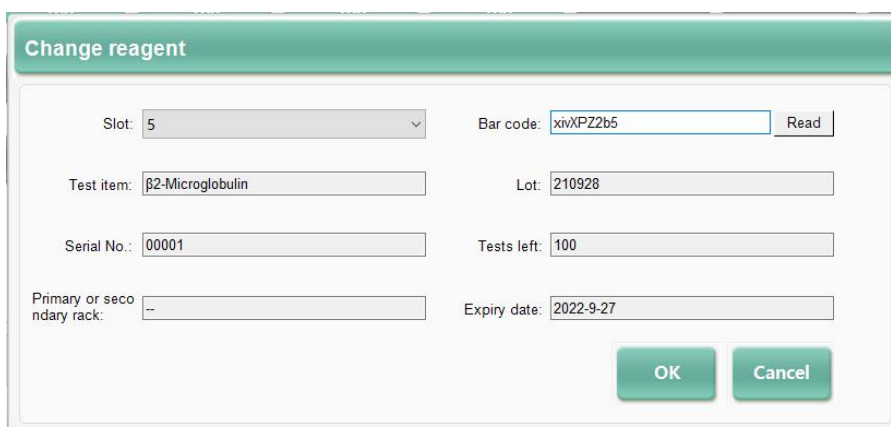
Change reagent						
Slot	Barcode	Test name	Lot	Serial No.	Expiry date	Tests left
1	xGW0UPgAu	AFP	210924	00003	12/31/2099	100
2	BGxYu1BnO0	CMV-IgM	210924	00008	12/31/2099	100
3	BkGRVWJyBu	25-OH VD	210924	00011	12/31/2099	100
4	BSPSovIrbz	CK-MB	210924	00010	12/31/2099	100

On-Board[4]	New[0]	Unload[1]	Error[0]	Unload	Manual Login	OK
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- 8) Select new installation button to view the list of newly installed kits;
  - 9) Click uninstalled button to view the list of uninstalled kits;
- Select the confirm replacement button;

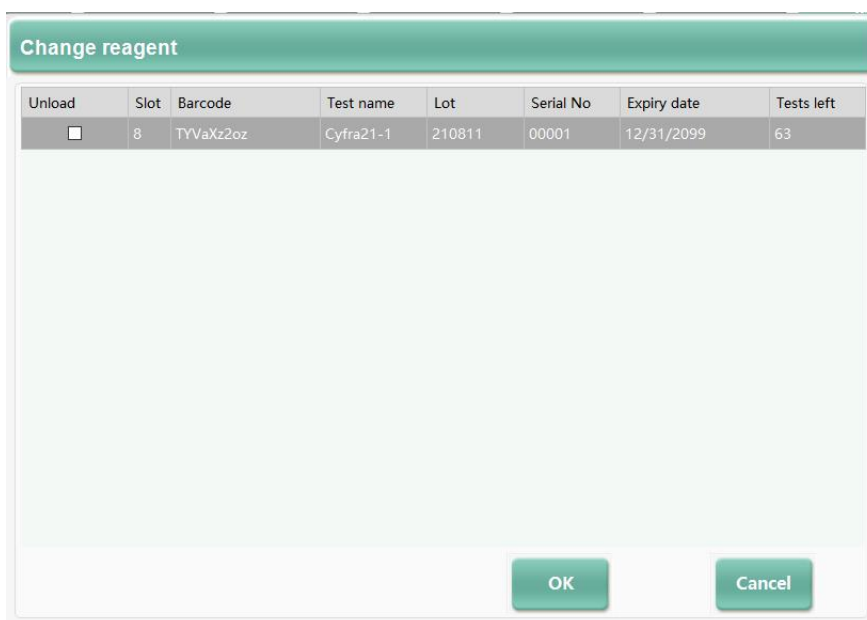




The image shows a 'Change reagent' dialog box with a green header. It contains several input fields and buttons. The fields are arranged in two columns. The first column includes a 'Slot' dropdown menu set to '5', a 'Test item' text box containing 'β2-Microglobulin', a 'Serial No.' text box containing '00001', and a 'Primary or secondary rack' dropdown menu set to '--'. The second column includes a 'Bar code' text box containing 'xivXPZ2b5' with a 'Read' button to its right, a 'Lot' text box containing '210928', a 'Tests left' text box containing '100', and an 'Expiry date' text box containing '2022-9-27'. At the bottom right of the dialog are two green buttons labeled 'OK' and 'Cancel'.

### 4.7.1.3 Unload Kit

- 1) Select the change Kit button to switch to the reagent change confirmation window;
- 2) Check the box of complete kit replacement on the instrument;
- 3) Select the change button;
- 4) After the instrument scanning kit is completed, the list of kits currently on the instrument will be displayed.
- 5) Click the unload button to enter the interface of unload kit. Select the kit you want to unload and click OK. Then wait for the instrument to unload the kit and click the OK button.
- 6) Open the cover of the reagent tray;
- 7) Take out the unloaded kit;
- 8) Close the cover of the test tray.



#### 4.7.1.4 Reagent Change Order

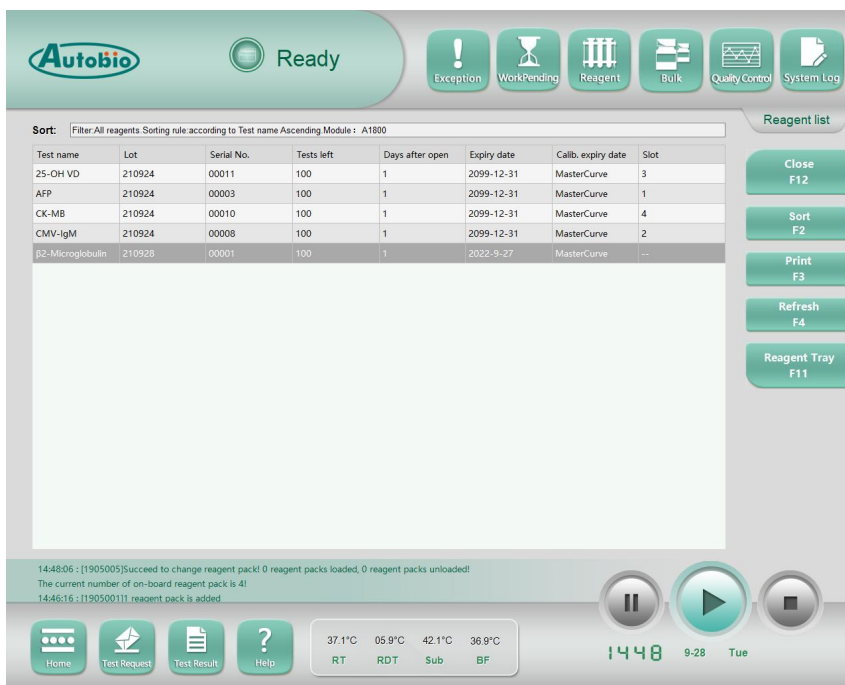
When the state of the instrument is “Running”, “Pause” or “Ready”, the reagent replacement operation can be performed by order. When making order to change the reagent, you need to hold down the REAGENT ORDER/TURN button on the instrument until the software interface indicates a successful order, a change countdown, or a pop-up that says, “The instrument is now ready to change reagents.” At this time, the reagent button indicator is off, and the kit can be replaced.

When the box “The instrument is ready to change reagents now” pops up on the software interface, you can open the cover of the reagent unit to change the kit, then close the cover of the reagent unit, and press the reagent order button on the instrument again to enter the process of changing the kit.



#### 4.7.2 Kit List

On the kit management interface, click the Kit List button to enter the kit list management interface.



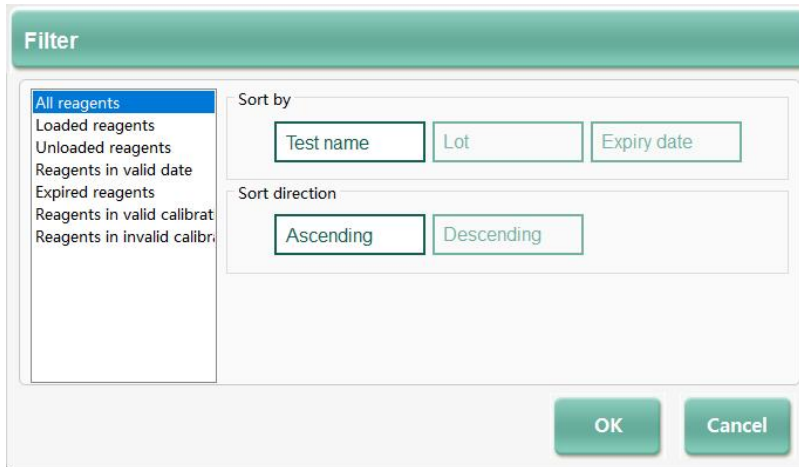
**NOTE:**

- 1) When the reagent has been unloaded, "--" is displayed in the slot field;
- 2) If the reagent has exceeded the expiry date or the calibration expiry date, the text will be displayed in red.

Name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If you enter this interface directly from the main interface, return to the main interface directly
Sort	Set screening conditions and screen kit records according to the conditions
Print	Print a list of screened kits and the information they contain
Refresh	Refresh the kit in the instrument
Reagent tray	Display all kits available for the instrument

**4.7.2.1 Sort Kit List**

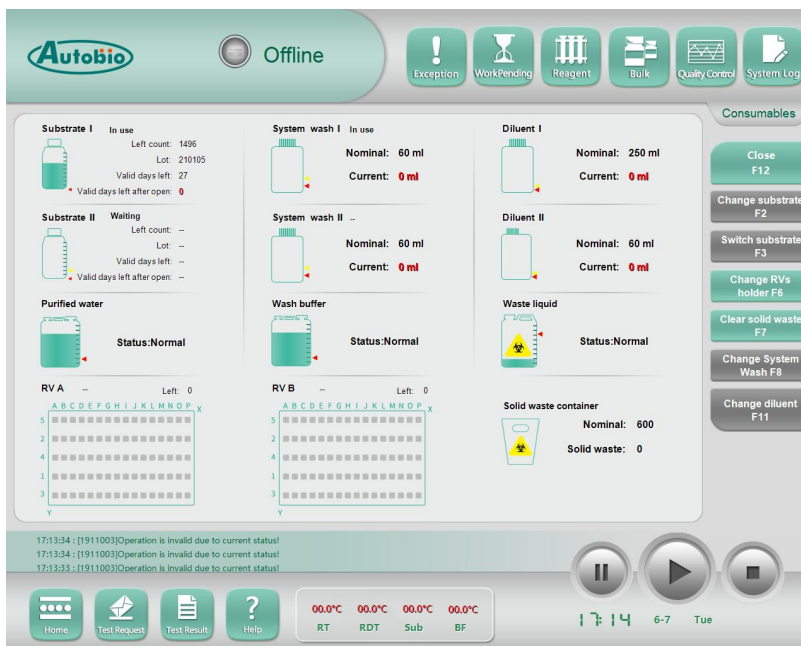
- 1) Select the sort button to switch to the screening condition setting dialog box;



- 2) Select screening conditions;
- 3) Select the sorting basis;
- 4) Select the sorting direction;
- 5) Click OK button.

### 4.7.3 Large Capacity Consumables

Click the consumables button in the upper right corner to enter the following large capacity consumables window:



**Window description:**

Name	Description
Close	Exit this interface and return to the corresponding secondary navigation interface (detection and analysis, maintenance, diagnosis). If you enter this interface directly from the main interface, return to the main interface directly
Change substrate	Change the luminescent substrate of the instrument, the button is not available if the system is not ready
Switch the substrate	To switch from one set of substrates to another, the button is not available if the system is not ready
Change RVs	Scan the bar code of reaction vessels to increase the number of available reaction vessels
Change reaction vessel holder	Change the reaction vessel holder on the instrument. The reaction vessel holder in use is not replaceable
Clean solid waste	Empty the solid bin, the quantity goes to 0
Change system wash	Change the system wash on the instrument. If the system is not ready, the button is unavailable
Change diluent	Change the diluent on the instrument, the button is not available if the system is not ready

**4.7.3.1 Change Substrate**

1) In the consumables window, select the “Substrate Management” button, and the following dialog box will pop up. By default, the current channel will be changed with substrate I. If “Substrate II” is selected in the red box below, substrate 2 will be chosen;

Substrate management

**Register substrate**

**Unload substrate**

Start

R5

Barcode:

Name:

Lot:

Expiration:

Tests left:

R6

Barcode:

Name:

Lot:

Expiration:

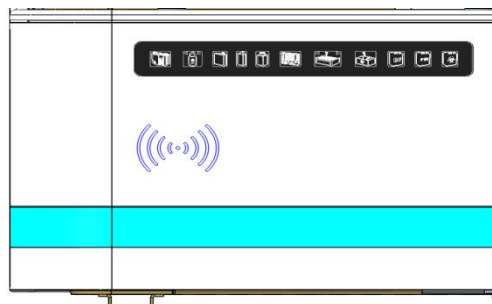
Tests left:

Note: After clicking start button, please aim the substrate RFID and stay in the RFID area of instrument.

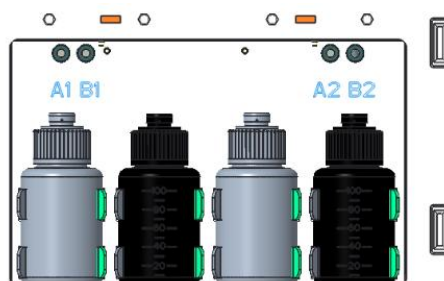
Ok

Exit

2 ) Scan the bar code /RFID on the luminescent substrate bottle that needs to be loaded;



3) Open the left front door of the instrument;



4) Observe the indicator light above the substrate bottle: when the orange light blinks, it can be replaced; when the orange light is on, it cannot be replaced;

5) Remove the substrate bottles from the rack, and put the used substrate bottles into the biological waste bag for waste;

6) Install new luminescent substrate bottles;

7) Close the left front door of the instrument;

8) Click the OK button on the computer interface;

9) After the replacement, the instrument will automatically fill the pipeline with substrate.



**CAUTION:**

1) In the running state, when the substrate is insufficient, the system will prompt the user to replace the substrate. At this point, no new tests are planned, but the current planned tests will continue, and new tests can be planned only after the current tests have been completed.

2) In the ready and pause state, change substrate button is optional, please perform the substrate replacement operation in time.

3) When the substrate is insufficient, one-stop display lamp flashes to alarm.

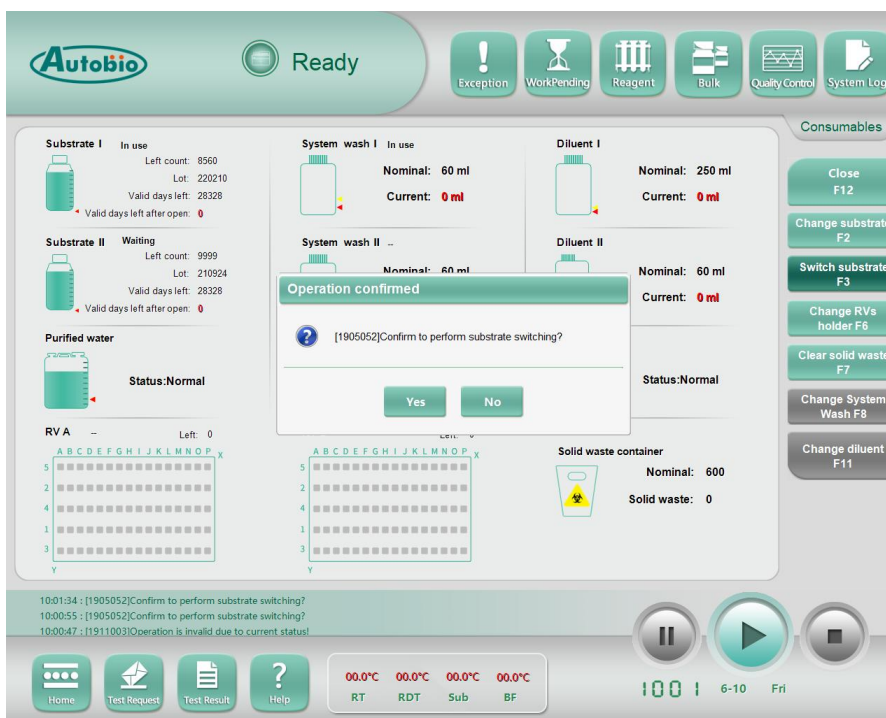


**WARNING:**

During these steps, you will be exposed to potentially infectious materials. Handle and dispose of these biologically hazardous materials in accordance with proper laboratory procedures. Proper protection must be taken for hands, eyes and face.

### 4.7.3.2 Switch the Luminescent Substrate

1) Select the switch substrate button in the consumables window, and the following dialog box will pop up:



2) Click Yes button;

3) After the switch is completed, the instrument will automatically perform pipeline perfusion.



**CAUTION:**

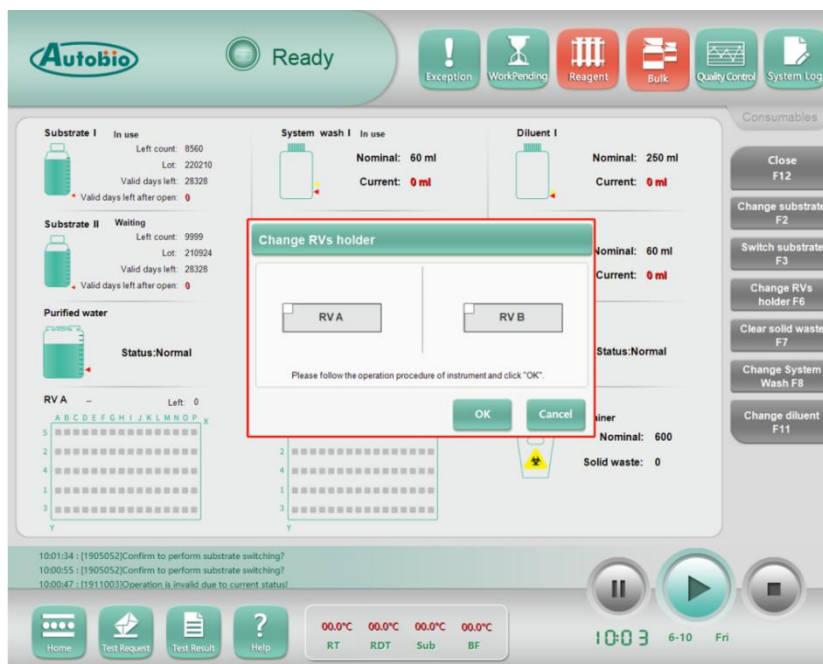
Do not manually switch substrates in the running state. If substrates are loaded in both channels, the system automatically switches substrates after the last test is completed without manual intervention. The new test can be performed only after the switchover is complete.

### 4.7.3.3 Add Reaction Vessel

Select the add reaction vessel button to switch to the load consumable - add reaction vessel dialog box;

### 4.7.3.4 Change Reaction Vessel Holder

1) In the consumables window, select the change RV holder button. In the following dialog box, select the channel to be changed;



2) Manually change the reaction vessel holder;

3) Click the OK button on the computer, and the interface will be updated accordingly.



**CAUTION:**



The sample rack in use cannot be changed while the experiment is being conducted.

### 4.7.3.5 Clean up Solid Waste

1) Pull down the “Rat-proof board” on the right of the instrument as shown below to temporarily block the waste reaction vessel, pour out the waste reaction vessel, load the solid waste box to the instrument, and the “rat-proof board” will automatically rise:



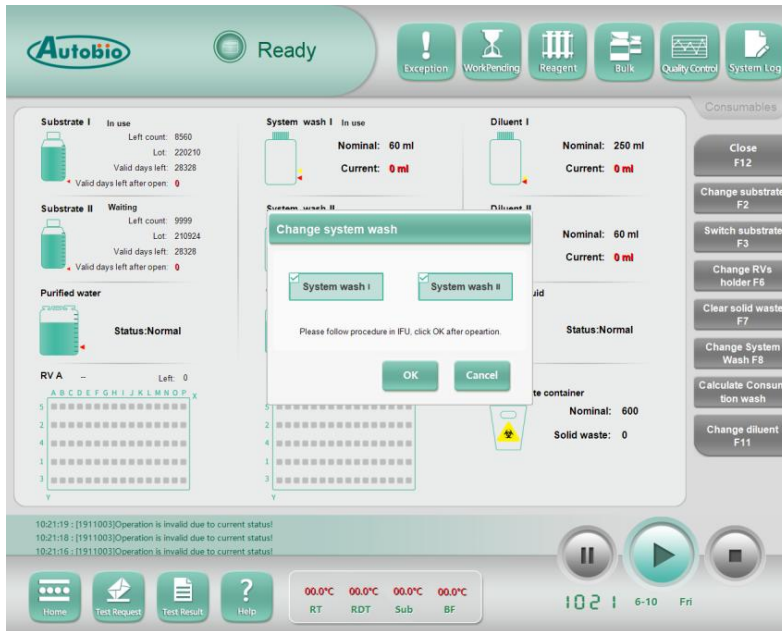
2) In the consumables window, select the clean up solid waste button and enter the confirm button in the following dialog box;

The screenshot displays the Autobio software interface. At the top, the status is 'Ready'. The main area is divided into sections for consumables: Substrate I (In use, Left count: 8560, Lot: 220210, Valid days left after open: 0), Substrate II (Waiting, Left count: 9999, Lot: 210924, Valid days left after open: 0), Purified water (Status: Normal), System wash I (In use, Nominal: 60 ml, Current: 0 ml), Diluent I (In use, Nominal: 250 ml, Current: 0 ml), and Diluent II (Nominal: 60 ml, Current: 0 ml, Status: Normal). A 'Clear solid waste' dialog box is open, prompting the user to follow the procedure in the IFU and click OK. The bottom status bar shows temperatures of 00.0°C for RT, RDT, Sub, and BF, a timer of 1005, and the date 6-10 Fri.

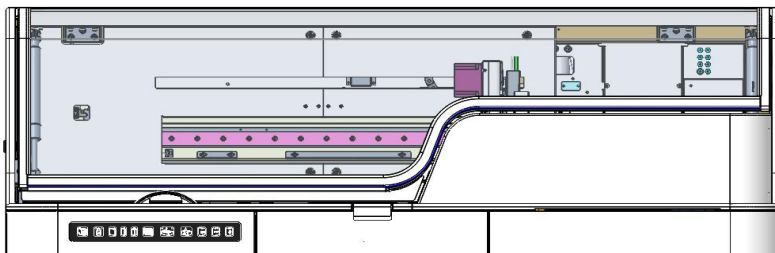
3) Click the OK button, and the interface will be cleared accordingly;

### 4.7.3.6 Change the system Wash

1) In the consumables window, select change system wash button. In the following dialog box, select the system wash channel;

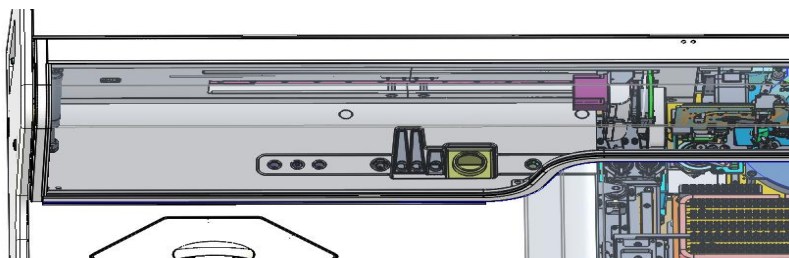


2) Open the upper cover;



3) Unload the system wash bottle that needs to be replaced and put it into the biological waste bag;

4) Load the new system wash bottle on the corresponding position of the instrument;



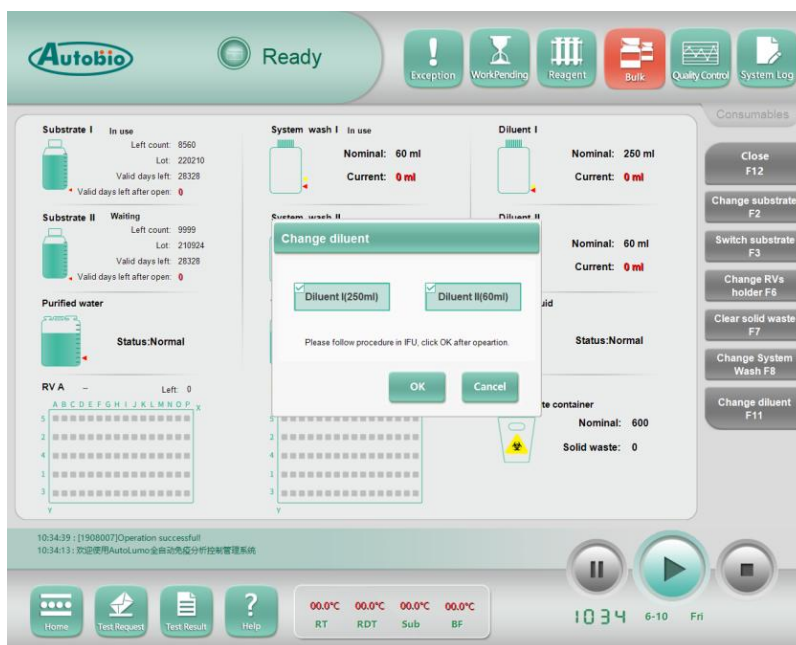
- 5) Close the cover of the instrument;
- 6) Click OK button.



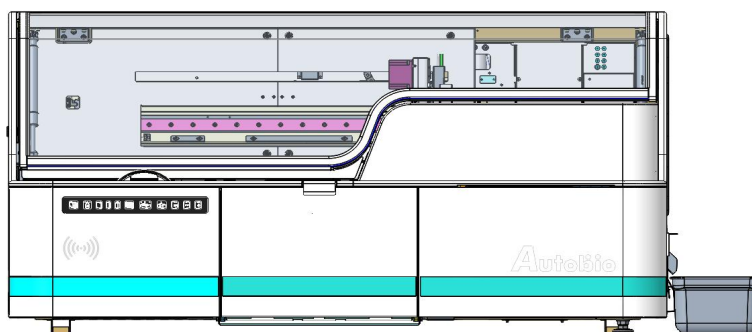
During the experiment, please ensure that sufficient system wash has been placed at the position of the system wash. If the system wash is insufficient during the experiment, the instrument will automatically alarm. At this time, you need to manually add the system wash and click change the system wash on the consumables interface, the system will automatically detect and cancel the alarm.

### 4.7.3.7 Change the Diluent

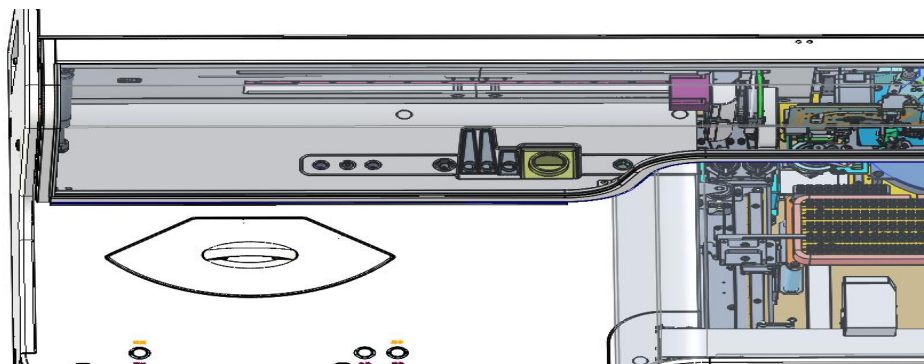
- 1) In the consumables window, select the change diluent button, and the following dialog box pops up, select dilute bottle;



- 2) Open the large up cover of the instrument;



- 1) Unload the diluent bottle to be replaced and put it into the biological waste bag;
- 2) Load the new diluent bottle on the corresponding position of the instrument;



- 3) Close the upper cover;
- 4) Click OK on the computer interface.



**CAUTION:**

During the dilution experiment, please ensure that sufficient diluent has been placed at the dilution position. If the diluent is insufficient during the experiment, the instrument will automatically alarm. At this time, you need to manually add the diluent and click change diluent on the consumable interface, the system will automatically detect and cancel the alarm.

## 4.8 System Settings

### 4.8.1 System Settings



**Tip: System Settings require administrator rights**

The default system login role is operator, so you must enter the administrator password to log in to the system. If the login role is an administrator, you do not need to enter the password for system settings.

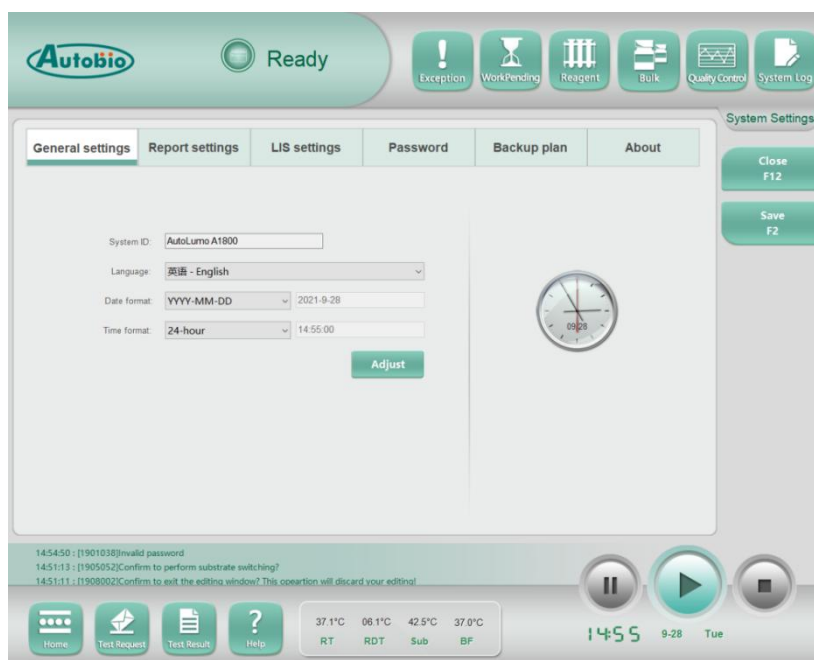
**System settings interface description:**

Name	Description
General settings	General settings include the system id, date format, time format, and system language.
Report settings	Set the system title information, printer selection, report configuration in the print report.

LIS communication settings	Set LIS communication parameters
Administrator password	Change the administrator password
Backup plan	Set data backup conditions
About	Display the system version information

- 1) After the setting is complete, click “Save” to make it take effect;
- 2) To cancel the operation, click [Close F12].

### 4.8.1.1 General Settings



Enter the system settings interface. The system settings interface is displayed by default.

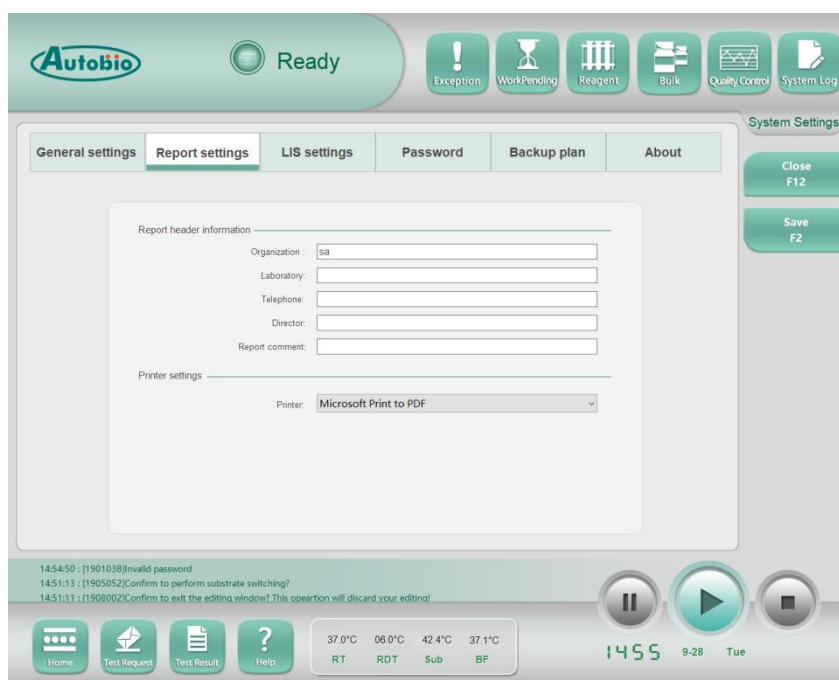
#### General settings interface description:

Name	Description
System identification	Set the system id. You can enter 1-24 characters as remarks. There is no special requirement for the software.
System language	The options for setting the system language include (Chinese(Simplified, PRC)-Chinese (Simplified, PRC), English-English)

Date format	The options for setting the date format include (YYYY/MM/DD, YYYY.MM.DD, YYYY-MM-DD, MM/DD/YYYY, MM.DD.YYYY, MM-DD-YYYY)
Time format	The options for setting the time format include 24 hours or 12 hours.

- 1) After the setting is complete, click "Save" to make it take effect;
- 2) To cancel the operation, click [Close F12].

### 4.8.1.2 Report Settings



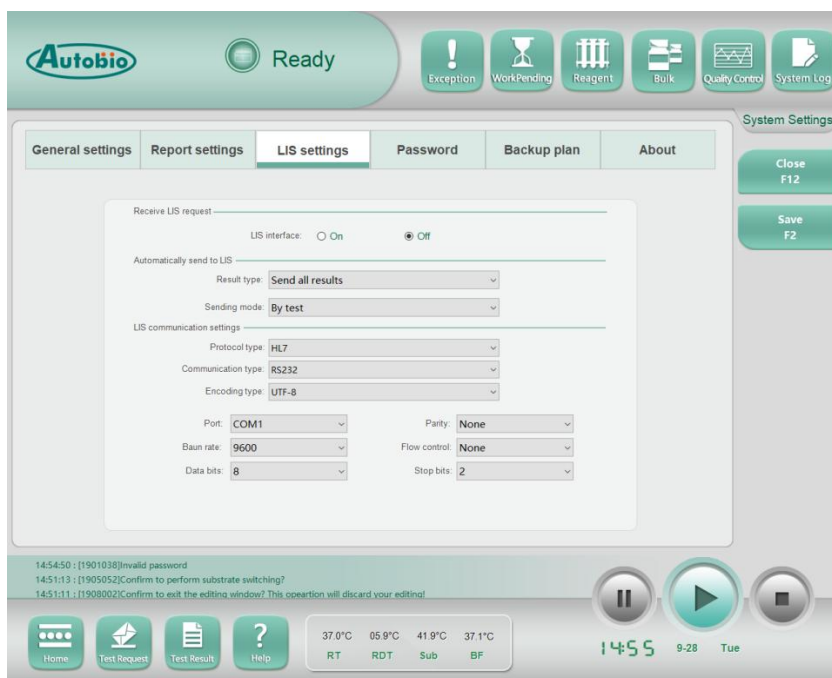
Report settings interface description:

Name	Description
Institution	Setting institution name
Laboratory name	Setting laboratory name
Tel	Setting Tel number
Director	Enter Director's name
Remarks on inspection report	Enter the remarks of the inspection report

Printer	Select printer
Report	Select a report type, if you need to change the report type, click Format adjustment to change

- 1) After the setting is complete, click “Save” to make it take effect;
- 2) To cancel the operation, click [Close F12].

### 4.8.1.3 LIS Communication Settings



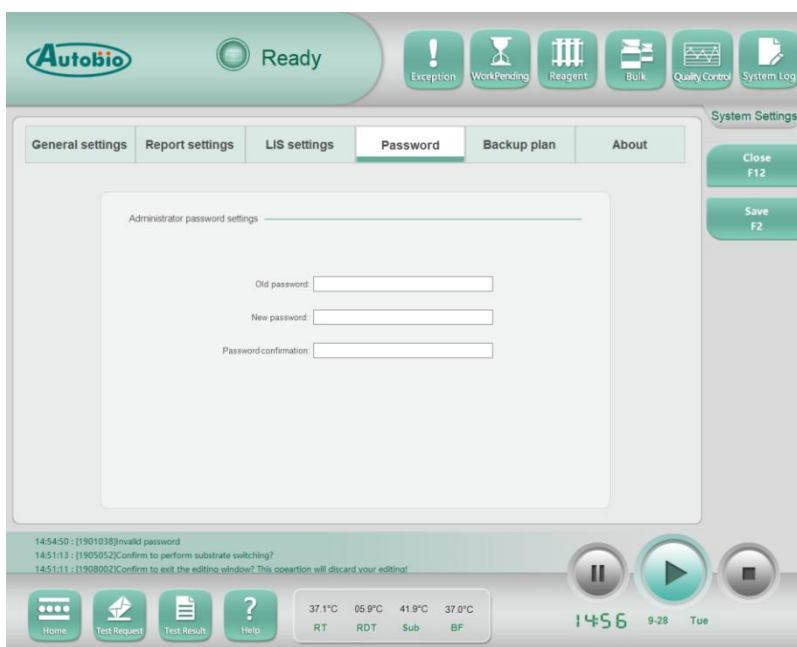
#### LIS communication parameter setting interface description:

Name	Description
LIS interface [Open]	Open the LIS communication port
LIS interface [Close]	Close the LIS communication port
Results type	Include (send all results, none)
Sending mode	LIS send mode settings, including (by test, by sample)
Port	Set the LIS communication port
Baud rate	Set the Baud rate of LIS communication
Data bits	Set LIS communication data bits

Parity	Set LIS communication parity parameters
Flow control	Set LIS communication flow control
Stop bit	Set the LIS communication stop bit

- 1) After the setting is complete, click “Save” to make it take effect;
- 2) To cancel the operation, click [Close F12].

#### 4.8.1.4 Administrator Password



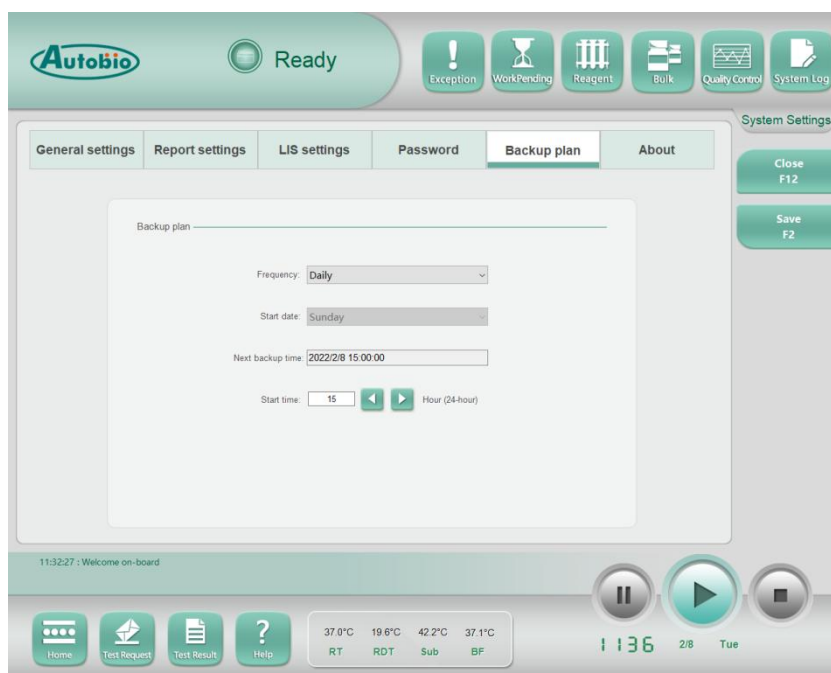
#### Administrator password interface description

Name	Description
Old password	Enter the old password of the administrator
New password	Enter the new password that the administrator wants to change
Repeat the new password	Enter the new password again

- 1) After the setting is complete, click “Save” to make it take effect;
- 2) To cancel the operation, click [Close F12].

#### 4.8.1.5 Backup Plan





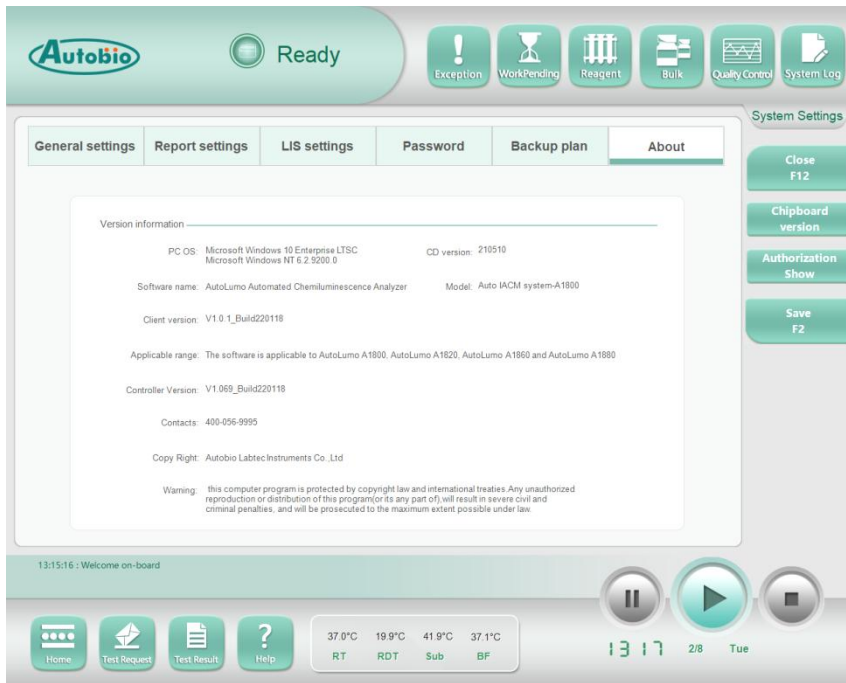
### Version Interface description

Name	Description
Backup cycle	Set how often to back up the data. Cycle settings include (daily, weekly)
Start backup date	Set the date to start backup. The options for setting the date include Monday, Tuesday, Wednesday, Thursday, Friday, Saturday, and Sunday.
Time to the next backup	Displays the time to the next backup
Start backup time	Set the time to start backup. The options for setting the time include (0 to 24)

- 1) After the setting is complete, click save to make it take effect;
- 2) To cancel the operation, click [Close this window F12].

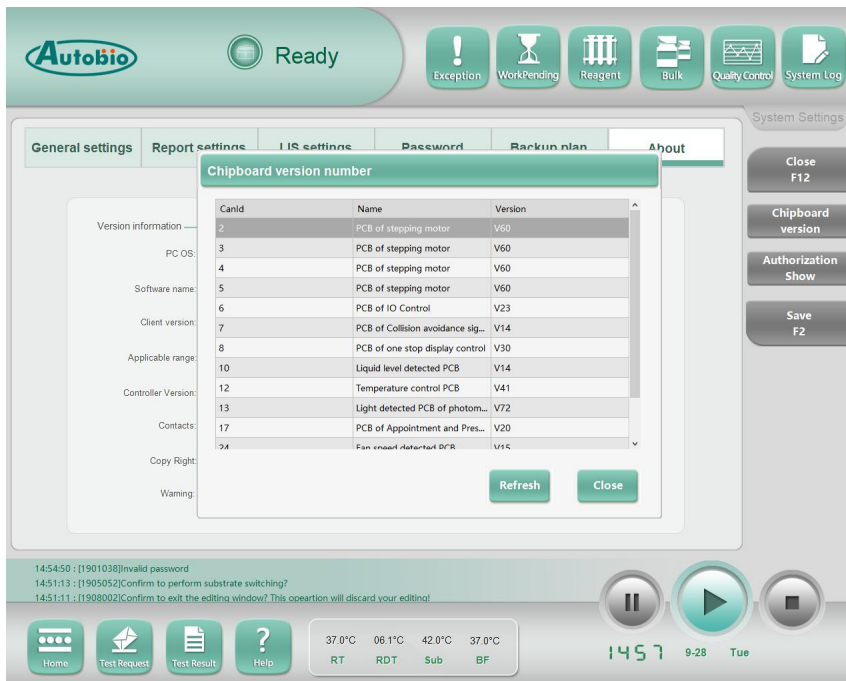
#### 4.8.1.6 About the System

For users to view the system version information, the software release version is V1.



#### 4.8.1.7 Circuit Version Number

With the permission of a maintainer, users can obtain the version number and Can ID number of each circuit board on the controller through the client software.



## 4.8.2 Test Item



**Tip: Test item operations require administrator rights**

On the main interface, select Detection and Analysis to enter the Detection and Analysis-Wizard interface. Select Test Item Parameter to switch to the test item window.

### Test item interface description

Name	Description
Test item	Display test item information
Sort	The screening test items are displayed based on the screening criteria
Edit	Edit test item parameters
Print	Print test items
Update	Update test items

To cancel the operation, click [Close F12].

### 4.8.2.1 Sort

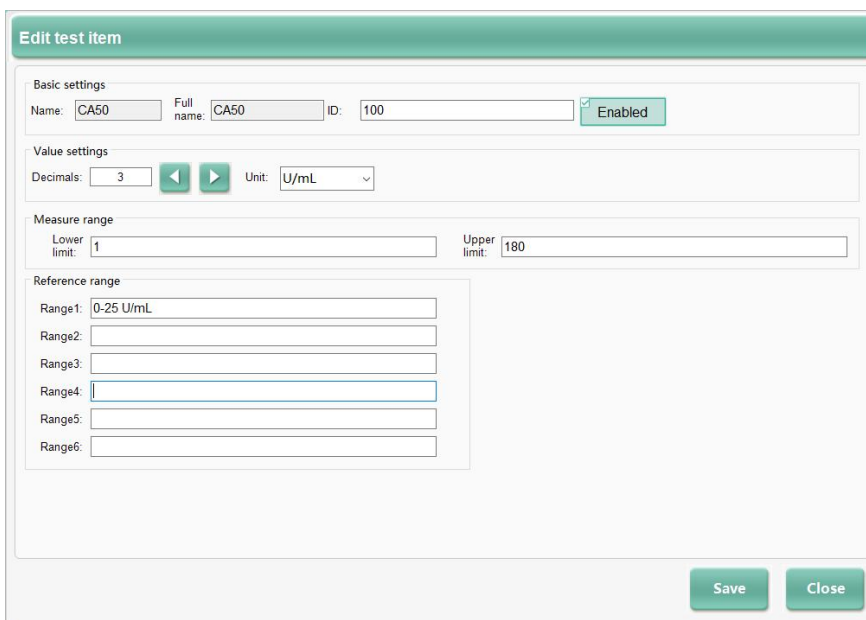
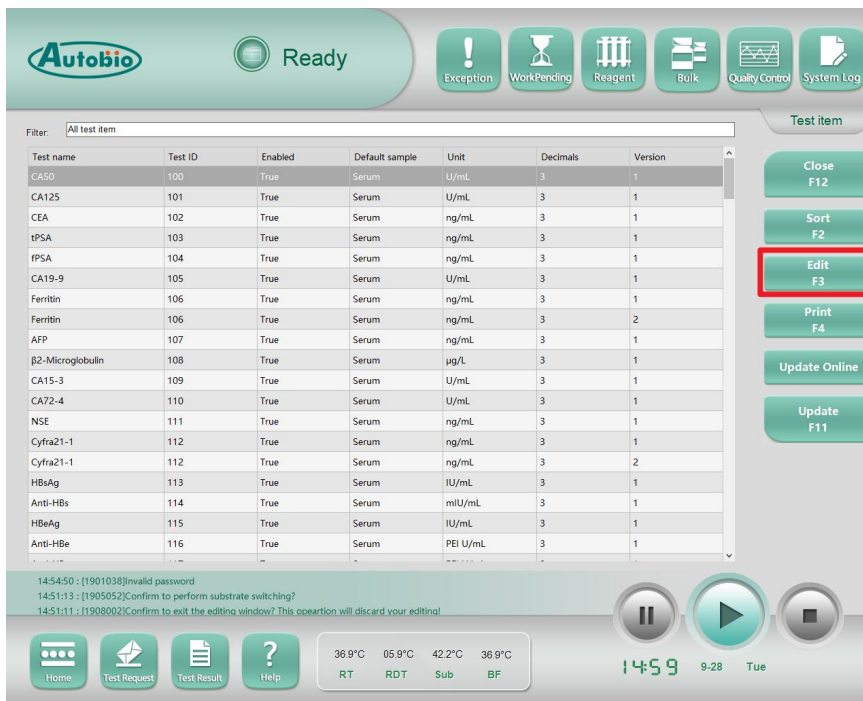
Click the sort button to display the sorting dialog box.

Screen interface description

Name		Description
Range	Name (all tests)	Enter the name of the test item you want to find and look it up across all test items
	Name (enabled)	Enter the name of the test item you want to find and look it up in the enabled test item
	Name (not enabled)	Enter the name of the test item you want to find, and look up the test items that is not enabled
Sorting		Sort choices include (name, test ID, enable, default sample, unit, decimal place, version)
Ascending		Sort in ascending order by the selected keyword
Descending		Sort in descending order by the selected keyword

- 1) If you confirm the Screening, click “OK”.
- 2) To cancel the operation, click “Cancel”.

**4.8.2.2 Test Item Editing**



Description of test item editing interface

Name		Description
Basic settings	Item name	Display item name, which cannot be edited

	Full name	Displays the full name of the test item name and cannot be edited
	Serial number	Edit the test item number. Enter the number range (integer 100-999). Duplicate test item numbers are not allowed
	Decimal digits	Sets the number of decimal places (integers 0-5) to be retained in the test results, and the results beyond the number of digits are rounded off
	Unit	Sets the units in which test result data is displayed. The unit options include (IU/mL, mIU/mL, NCU/mL, ng/dL, ng/mL, pg/mL, U/mL, $\mu$ IU/mL, pmol/L)
	Enable	Whether the user enabled the test item
Measure range	Lower limit	Minimum detection range
	Upper limit	Maximum detection range
Reference range		<p>Range 1, Range 2, range 3, range 4, range 5, range 6, reference ranges (0-60 characters) for the print-out display of the report of test results corresponding to this test item</p> <p>Note: In the current report, do not print the set reference range</p>
Qualitative judgment (qualitative)	Gray area upper limit	The upper limit of gray area is the area greater than or equal to the critical value
	Gray area lower limit	The lower gray limit is the area that is less than or equal to the critical value
	Less than the lower limit of gray area	The judgment result that the current value is less than the lower limit of gray area
	Judgment results in the gray area	The judgment result that the current value is between the upper limit and lower limit of the gray area
	Greater than the	The judgment result that the current value is greater than the upper limit of gray area

	upper limit of gray area	
Critical range (quantitative)	Critical value 1	Define threshold 1 for quantitative items
	Critical value 2	Define threshold 2 for quantitative items
	Less than the critical value 1	The judgment result that the current value is less than the critical value 1
	Results between critical values 1 and 2	The judgment result that the current value is between the critical value 1 and the critical value 2
	Greater than the critical value 2	The result that the current value is greater than the critical value 2

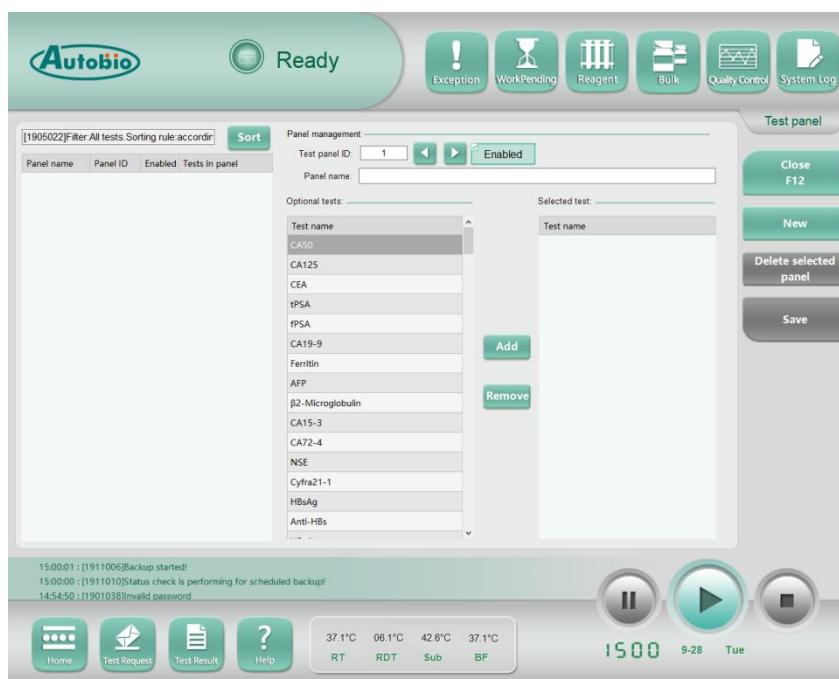
- 1) If you confirm to save, click "OK";
- 2) To cancel the operation, click "Cancel".

### 4.8.3 Test Combination



**Tip: The test combination operation requires administrator rights**

On the main interface, select Detection and Analysis to enter the Detection and Analysis-Wizard interface, and click Test Combination to switch to the test combination window.



Description of test combination interface:

Name	Description
New	Create a new test combination
Delete selected combination	Deletes a selected test combination
Save	Save the changes
Test combination ID	The selected test ID is the same as the optional test ID and cannot be changed
Enable	Whether to enable the current test combination
Sample type	Select the type of test sample
Combination name	Edit an existing test combination name or enter a new test combination name
Optional test	Displays the current sample type available for selection of test items
Selected test	Displays the test items that have been added to the current test combination
Add	Add selected test items from the optional test list. You can add



	multiple test items or add them repeatedly
Remove	Removes selected test items

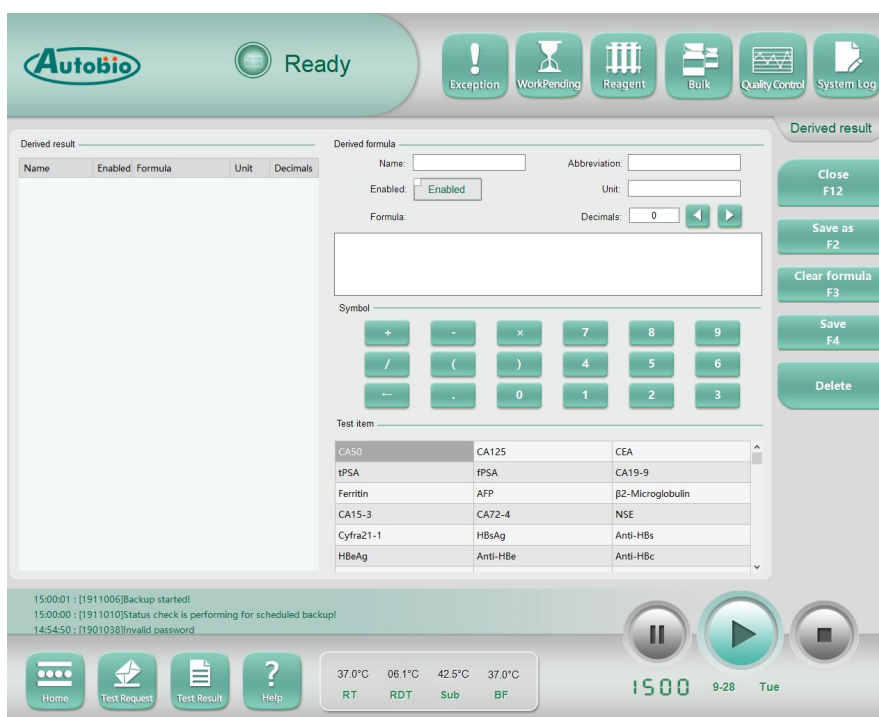
- 1) If you confirm to save, click "OK";
- 2) To cancel the operation, click "Cancel";
- 3) To close the window, click "Close this window F12".

### 4.8.4 Results Derived



**Tip: operations of deriving result require administrator rights**

Results derived refer to the derivation of a new result by using the existing results of one or more test items through four arithmetic operations (addition, subtraction, multiplication and division), which is considered as a new test item. When all tests of the patient samples are completed, a new result data is generated according to the derivation of results rules.



#### Results derived interface description

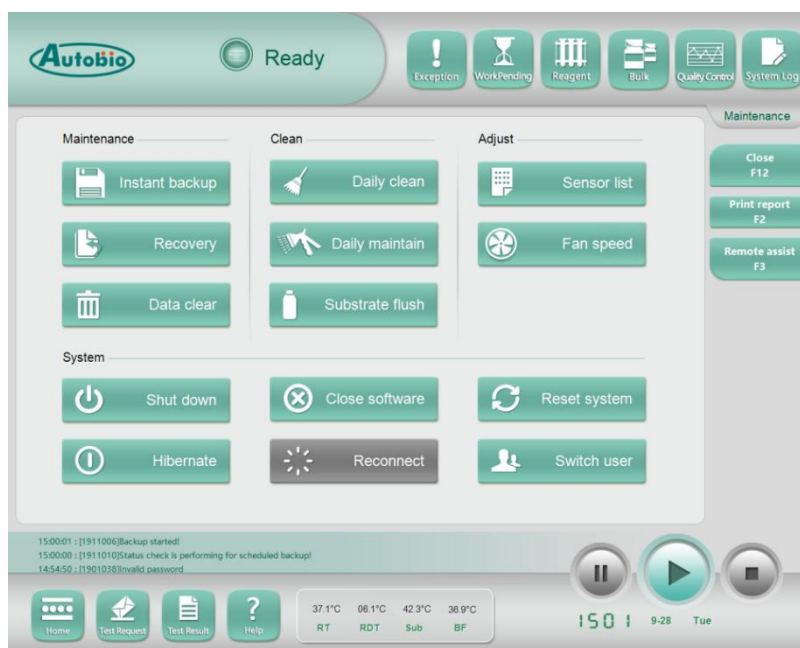
Name		Description
Existing results derived		Displays the existing derivation result information
Formula	Name	Sets the derivation formula name

derived	Unit	Sets the units in which test result data displayed
	Enable	Whether to enable the current results derived
	Decimal digits	Sets the decimal digits of test result data
	Formula	Enter or edit the current derivation formula
Symbol		Provides input buttons for editing derived formulas
Test item		Displays the currently available test items
Save one		Saves the current formula and allows editing of new formulas
Clear formula		Clears information in the current result text box
Save the current		Saves the current creation and overwrites the selected existing results derived, if you don't want to overwrite the existing results derived, click save
Delete		Deletes the currently selected result data

## 4.9 Maintenance

The system maintenance menu provides items for instrument maintenance, to ensure the normal running of the instrument, maintain the instrument and system according to the system maintenance requirements. If the damage is caused by improper maintenance, the maintenance cost shall be borne by the user.

Select maintenance from the main interface to enter the following interface:

**NOTE:**

Some menus may not be displayed due to system permissions. These menus need to be displayed in a specific administrator action mode. If you need to make adjustments to these items, please contact our engineers to determine if you can maintain and adjust the items.

### 4.9.1 Backup and Recovery

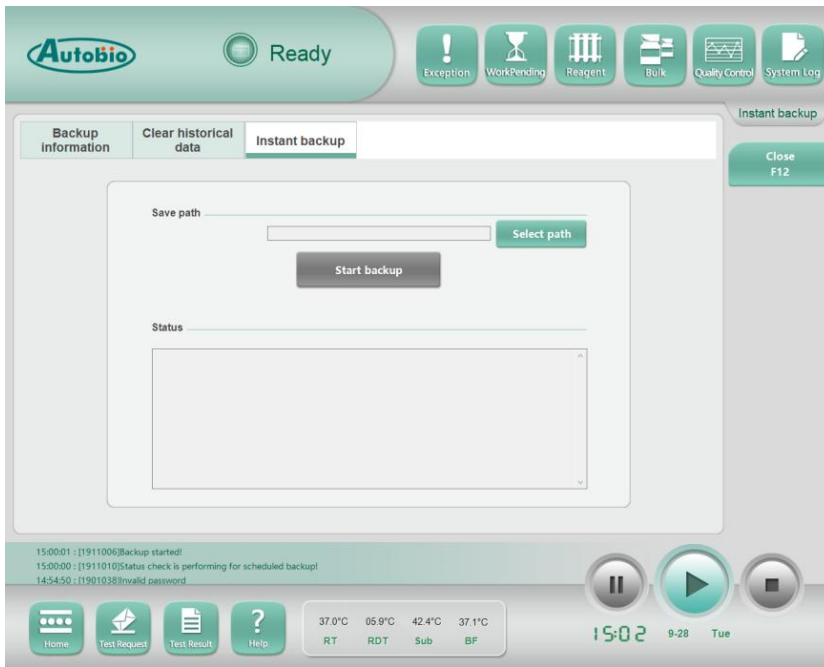


**Tip: Maintenance operations require administrator rights**

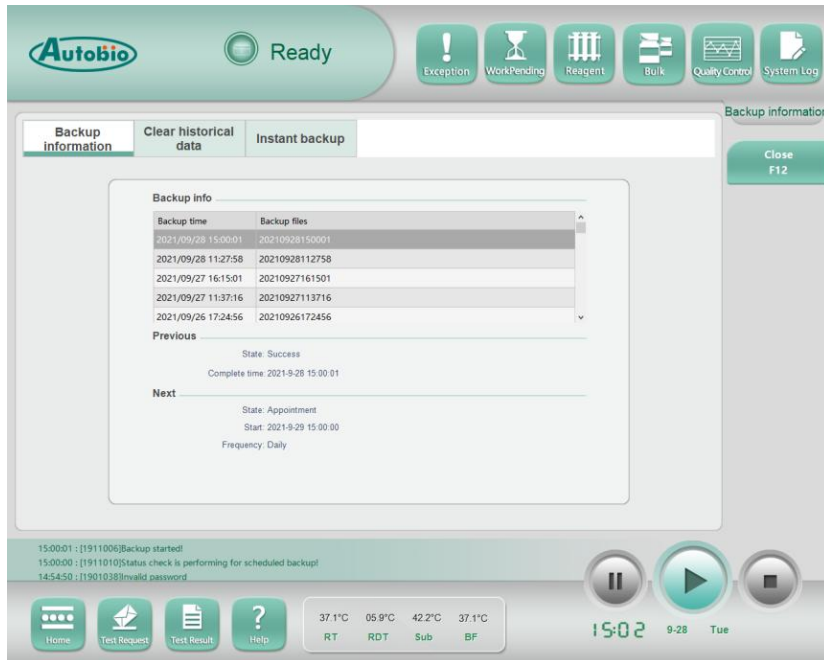
The maintenance menu includes instant backup, recovery system, and historical data clearing.

**Instant backup:**

You can back up the database to prevent database data loss due to database damage or misoperations. You can select a backup location to back it up (Default path: D:\Bak).

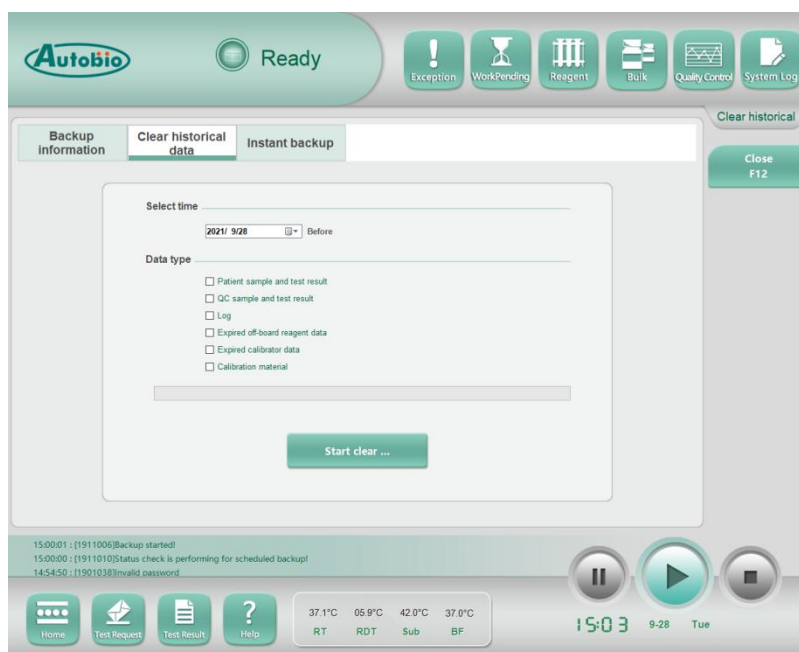


After the backup is complete, you can select information to view the backup details, including backup status, backup time, and storage location. See the figure below



### Historical data clearing:

You can also select the time and data type to delete unnecessary records on the clear history page. This operation cannot be restored. You are advised to confirm the data to be deleted before performing this operation.



### Recovery system:

Select recovery system. A dialog box will be displayed asking whether to restore the entire system. Select yes or no. After the system is restored, the system will be initialized. Therefore, you must back up the database before restoring the system to prevent database damage and data loss caused by incorrect restoration.



### CAUTION:

Recovery system operation can only be performed by manufacturer or agent!

## 4.9.2 Clean

### Daily clean

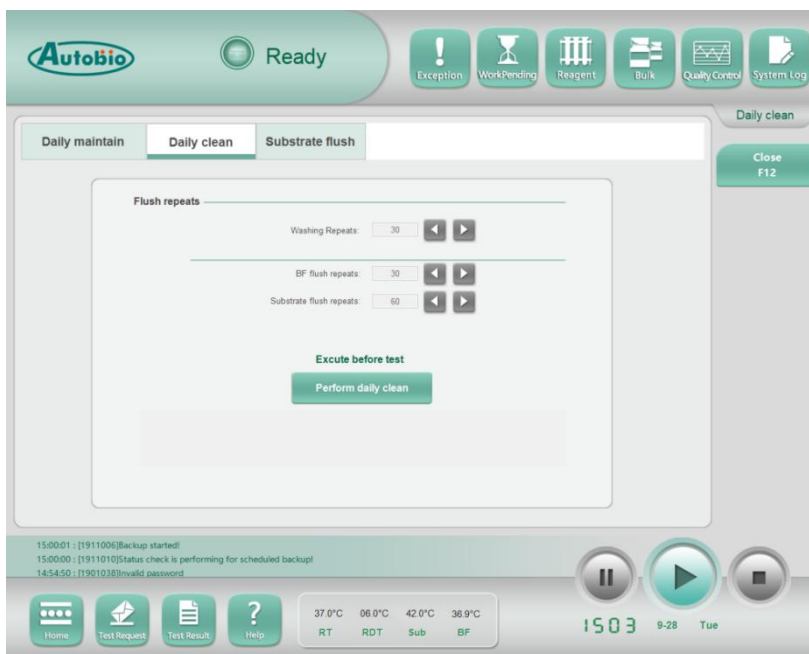
Cleaning procedures should be performed each day before the start of the experiment. It is recommended that the internal and external washing times of the sample probe should not be less than 10 times, the BF washing times should not be less than 20 times, and the substrate washing times should not be less than 60 times (50ul per time). Daily clean operations are shown in the following figure.

Adjust the clean times by the up and down arrow or directly enter the clean times (maintenance permission), and click to perform routine cleaning. The routine cleaning progress will be displayed at the bottom of the screen. Do not try to stop the process of the instrument during the cleaning process, so as to avoid database damage or operation failure.



**CAUTION:**

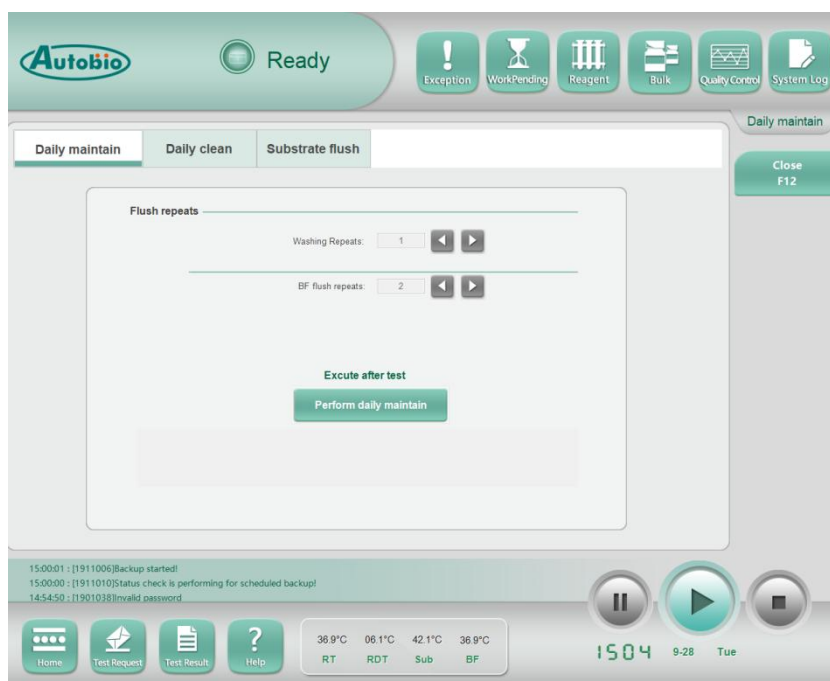
Because the substrate nozzle has the function of heating pretreatment, the substrate in high temperature for too long will affect the results of the experiment, please strictly follow the cleaning procedures.



**Daily maintain**

The system will automatically perform daily maintenance every day after the completion of the test and before the software is shut down. Users do not need to manually perform daily maintenance.

For special conditions, if the customer service staff has confirmed with the customer that daily maintenance is required manually, it is recommended that you carry out daily maintenance after the end of the daily experiment. Wash the sample probe inside and outside at least 10 times, BF wash not less than 20 times, adjust the cleaning times through the left and right arrows or directly input the cleaning times (maintenance personnel permission). If your laboratory is to run the instrument continuously, daily maintenance should be performed after the longest idle period.



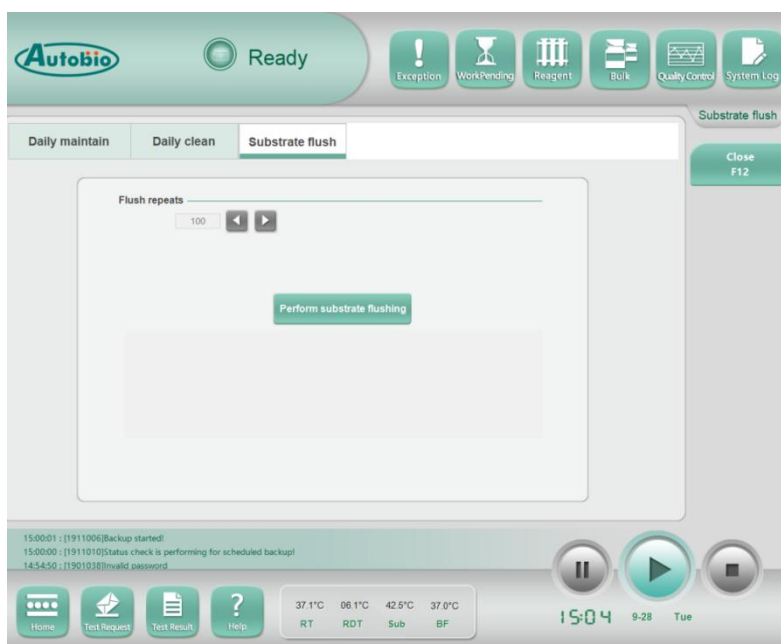
## Flush substrate pipeline

### Change substrate:

When change the substrate, the substrate tube should be pulled out from the substrate bottle first, and then emptied at least 30 times, and wiped the outer wall of the tubeline with purified water. After the drain, the substrate tube should be inserted into the new substrate bottle and rinsed at least 60 times (50ul per time).

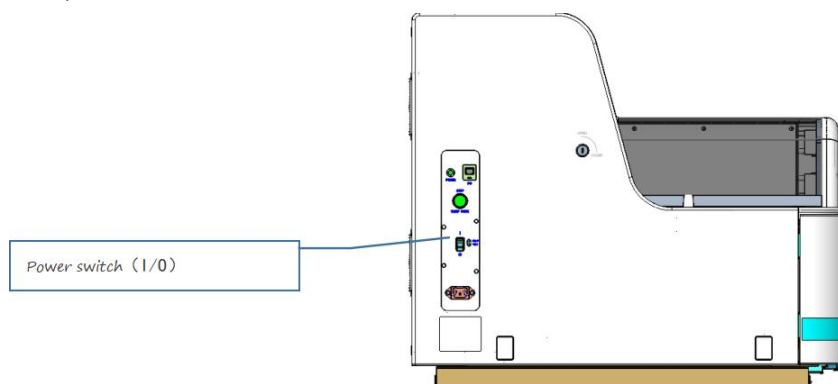
At least 60 times (50ul per time) substrate flush should be performed when the instrument is reused after a long period of inactivity.

Use the up and down arrow to adjust the flushing times or directly enter the flushing times (permission of maintainer), as shown in the following figure.



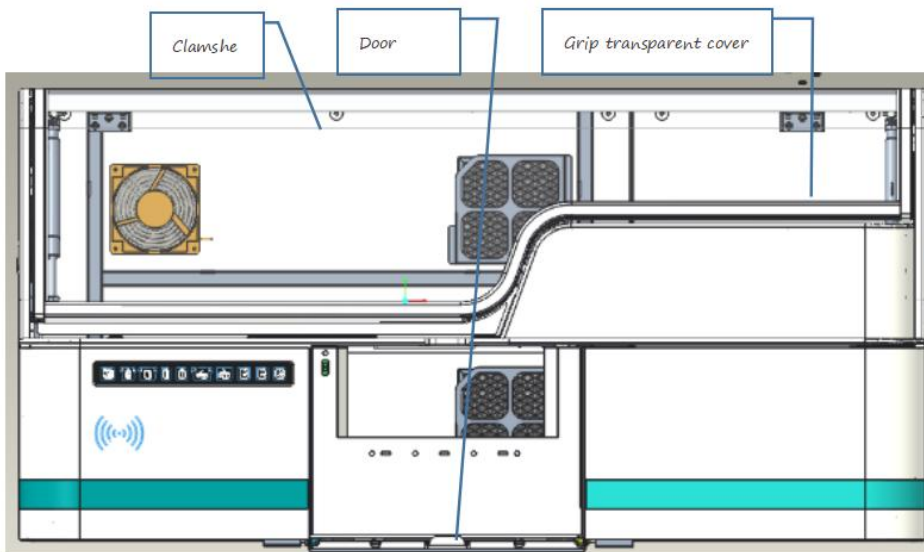
### 4.9.3 Clean the Interior of Instrument

1) Turn off the power switch on the side of the instrument.



2) Open the door in the instrument, the large clamshell cover and the transparent cover of the grip.





3) Wipe the sample loading table with a cloth containing water and neutral detergent or a trace amount of alcohol.



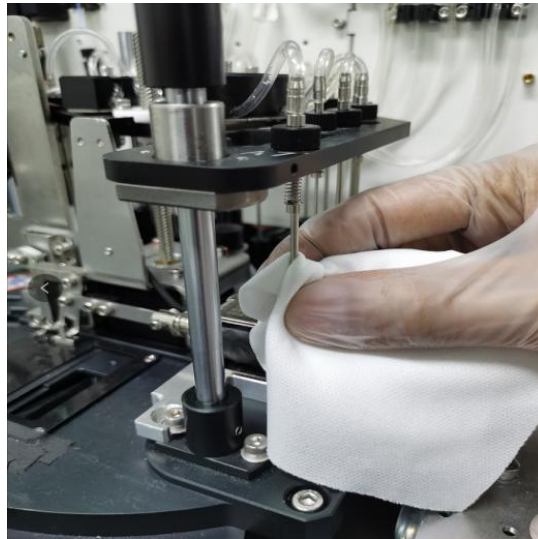
4) Use gauze containing water, neutral detergent or trace alcohol to wipe the surrounding stains such as reagent table and reaction container supply table.



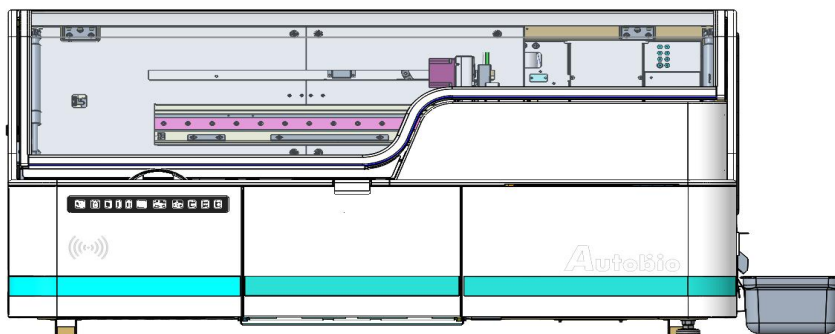
5) Wipe the sample probe with gauze containing a trace of alcohol.



6) Wipe the BF cleaning liquid injection probe and substrate probe with gauze containing trace alcohol.



7) After cleaning, cover the door, large clamshell and transparent cover in the instrument and make sure that the emergency stop device is normal.



**NOTE:**

Wash buffer and system wash can irritate eyes and skin. Proper laboratory procedures should be followed.

There may be a danger of electric shock during the wiping process. Please ensure that the instrument is powered off before operation.

In the process of wiping, do not use alcohol or other organic solvents to wipe the transparent acrylic, so as to avoid cracking of acrylic!

#### 4.9.4 Clean the External of Instrument

Turn off the power switch at the bottom right of the instrument, and wipe the instrument shell with a soft dry cloth dipped in a neutral lotion.

**NOTE:**

Do not use alcohol to wipe the non-metallic part of the instrument shell to avoid damage to the non-metallic shell!

To ensure the accuracy of the test results, it is recommended to periodically check and replace the pipeline of magnetic washing unit. For details, refer to the Service Manual. Replace the sample probe immediately when it is deformed.

The above operations need to be carried out by our engineers from Autobio. Please do not disassemble or assemble the instrument before the arrival of the professional engineers.

The container of wash buffer and purified water should be cleaned once a week (this operation should be carried out by the user).

The operator shall ensure that:

- a) Appropriate decontamination is carried out if hazardous material is spilled onto or into the equipment;
- b) Not using the decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it;
- c) The manufacturer or its agent is consulted if there is any doubt about the compatibility of decontamination or cleaning agents with parts of the equipment or with material contained in it.

**WARNING:**

During cleaning process, you will be exposed to potentially infectious materials. Follow proper laboratory procedures to handle and dispose of these biologically hazardous materials. Take necessary protection against your hands, eyes and face.

## 4.9.5 System

1) Shut down the system:

Shut down the software and computer if you intend to move the equipment or if you want to shut down the system for a long period (more than 5 days).

2) Instrument sleep:

When the instrument is not used for a long time, the instrument is selected to sleep to save energy. In the sleep state, the instrument will not be able to perform tests.

The cooling and heating of the instrument are still in operation.

3) Restart the system:

Restart the software and computer.

4) Wake up the instrument

Wake up the sleep instrument. After awakening, the instrument needs to be re-initialized before operation.

5) Reinitialize:

It's a process of initializing the control system and operating system in an unready state. The instrument will not operate during initialization.

6) User change:

Switch between users with different permissions.

## 4.9.6 Reinitialization

It's a process of initializing the control system and operating system in the "not ready" state. Select the item you want to initialize and perform the initialization operation. The system default initialization items are marked, and you can manually change the items that need to be initialized.

Item 1, 2, 4, 5, 6, 7, and 10 are required, and the others are optional. The third item is the remote LIS function of the instrument. Item 8 is not ticked for normal initialization, however, tick it when there are reaction vessels on incubation tray and sample, BF mixer and gripper. This parameter is not selected by default, but is selected by default on the previous test terminal. Item 9 should be selected when diluting items are initialized before testing.



### 4.9.7 Parts and consumables replacement/maintenance

Parts and consumables replacement/maintenance instructions are as follows:

Category	Name	Replacement/maintenance period	Change method	Note
Parts	Sample rack	Barcode damage and yearly replacement	Clean the dirt and change the bar code	Exclusive to the company
	System wash bottle	Dirty/ wash once a week	Fill the liquid and replace it	Exclusive to the company
	Waste liquid container	Dirty/clean once a week	Load after dumping the waste liquid	Exclusive to the company
	Wash buffer container	Dirty/clean once a month	Load after filling with wash buffer	Exclusive to the company
	Purified	Dirty/clean once a	Load after filling	Exclusive to the

	water container	month	with purified water	company
	Solid waste bin	Clean once a week with 84 disinfectant diluent;	Use the following solid waste bags	Exclusive to the company
Consumer goods	Reaction vessel	Disposable	Load before/during test	Exclusive to the company
	Sample cup	Disposable	Sampling with the new cup	Sample tube, test tube with diameter 12 - 16mm, 2ml microcup
Other	Emergency sample	Samples from emergency and non-emergency are common. There is no color or feature distinction requirement for the emergency sample rack, and the instrument does not identify the characteristics of the emergency sample rack. The emergency sample is only judged by whether there is a sample rack in the emergency channel. According to the actual needs, users can use a color sample rack for visual distinction. For specific emergency sample operation, please refer to the relevant instructions of emergency sample test in this manual.		
	Barcode	The bar code of sample rack and sample cup is one - dimensional bar code.		
Note: The above instructions do not include abnormal use of damaged parts. Damaged parts are recommended to replace immediately, please contact the manufacturer or agent.				

#### 4.9.8 List of Wearing Parts

The list of wearing parts and their replacement/maintenance instructions are as follows:

Category	Name	Replacement/maintenance period	Change method	Note
Wearing parts	Gripper cushion	One year	Pull into the grab hand to cut off the head, no	Gripper unit

			need to disassemble the instrument	
Gripper tension spring	Five year		Remove gripper pin and replace gripper pin	Gripper unit
Filter	3 months / 43,000 tests		Dismantle/do not dismantle the instrument, replace the liquid tube	Wash buffer container, purified water container, vacuum tank pressure relief valve, waste liquid container, pressure relief valve
Silencer filter element	6 months / 86,000 tests		Disassemble the instrument, replace the internal parts of liquid path	Vacuum system
Peristaltic pump hose	12 months / 172,000 tests		Disassemble the instrument and replace the back panel of the magnetic washing dish head and liquid path	Peristaltic pump unit
Peristaltic pump head	12 months / 172,000 tests		Open the observation door on the right side of the instrument and replace peristaltic pump head	Peristaltic pump unit
External tubes of the lotion bucket	12 months / 172,000 tests		Replace the external pipeline without disassembling the instrument	Wash buffer container, purified water container, waste liquid container
Fuse (250V 8A )	Five year		Disassemble electric control box, insert and replace fuse	Main fuse

Note: The above instructions do not include abnormal use of damaged parts. Damaged parts are recommended to replace immediately, please contact the manufacturer or agent to disassembly and replace the internal liquid circuit parts of the instrument.

### 4.9.9 Daily check

#### 1) Liquid path check

When the instrument is ready, perform daily clean operation to observe whether the liquid flow is normal, and check whether the tube is bent or blocked. If so, dredge it in time to keep the tube unblocked.



#### CAUTION:

Do not use organic solvents: organic solvents may damage hoses, bar code scanners, pumps, valves, housing, etc., causing damage to appearance and performance of the instrument.

#### 2) Software temperature check

After the temperature of each unit becomes stable, observe the temperature status displayed on the software. If the temperature exceeds the alarm temperature, the indicator is red. Contact technical support engineers for maintenance.

#### 3) Expiry date of reagent and calibration check

In the software, check the number of tests and expiration date of each test reagent. If the number of tests is insufficient, new reagents should be added; If the reagent exceeds the expiry date, a new reagent should be loaded and re-calibrated.

In the software, check the validity period of calibration of each test reagent. If the reagent calibration exceeds the expiry date, it needs to be re-calibrated.

#### 4) Consumables check

a) Check the number of reaction vessels on the reaction vessel loading unit, and add new reaction vessel holders in time;

b) Check the amount of diluent in dilution bottles I and II. If the height of the dilution is less than 3cm, it should be replaced or added, and "Replace diluent" should be performed on the consumables interface;

c) Check the remaining use times of the substrate in the software. If it is not enough for this experiment, it should be replaced in time;

d) Check the status of each lotion. If it does not meet the requirements for this experiment, please add it in time.



5) Clean up solid waste and waste liquid

a) Check the waste containers of reaction vessels. If the amount of waste cups exceeds 2/3 of the container, clean them up in time;

b) Check the waste liquid container. If the amount of waste liquid exceeds 2/3 of the container, it should be cleaned up in time.

6) Daily clean and maintain

a) In the "Maintenance" column, select "daily clean", flush the inner and outer wall of the probe 10 times, BF 20 times, substrate 60 times (50ul per time), and select "Perform daily clean" button;

b) After the experiment, select "Daily maintain" in the "Maintenance" column, flush the inner and outer wall of the probe for 10 times and BF for 20 times, and select "Perform daily maintain" button.

## 4.10 Experimental operation

The system test is divided into three modes: continuous test, random test and emergency operation. The test can be started after the samples are put into the sample management unit in continuous test or random test. The emergency samples should be put into the emergency channel of the sample management unit for test, and the emergency samples will be prioritized for test.



### CAUTION:

Do not open the big clamshell when the whole instrument is working to prevent damage to the probe or the operator!

Do not forcibly power off, strictly execute the operation of shutting down the mains supply after logging out the software, and regularly perform the backup to the system and data!

Only to ensure that each part is in the ready state, the system can be normally used for detection and analysis!

When using this product, a clinical diagnosis should not be made on the basis of the results of a single test, but only after the physician has evaluated all clinical and laboratory tests!

### 4.10.1 Preparation before test

#### 4.10.1.1 Check the position of the instrument (the instrument is off)

Open the front cover of the instrument and confirm as follows:

1) Open the clamshell of the instrument and confirm whether there is a reaction vessel on the cleaning metering unit and incubating unit. If there is a reaction vessel, please perform the operation of cleaning up the incubation tray;

- 2) Confirm that the sampling probe is above the washing station; If not, it can be moved into place manually;
- 3) Confirm that the cover of the reagent tray and the front and rear covers of the instrument are covered well;
- 4) Confirm that the arrangement of reaction vessels on the reaction vessel rack is consistent with the diagram of reaction vessels in the consumables interface;

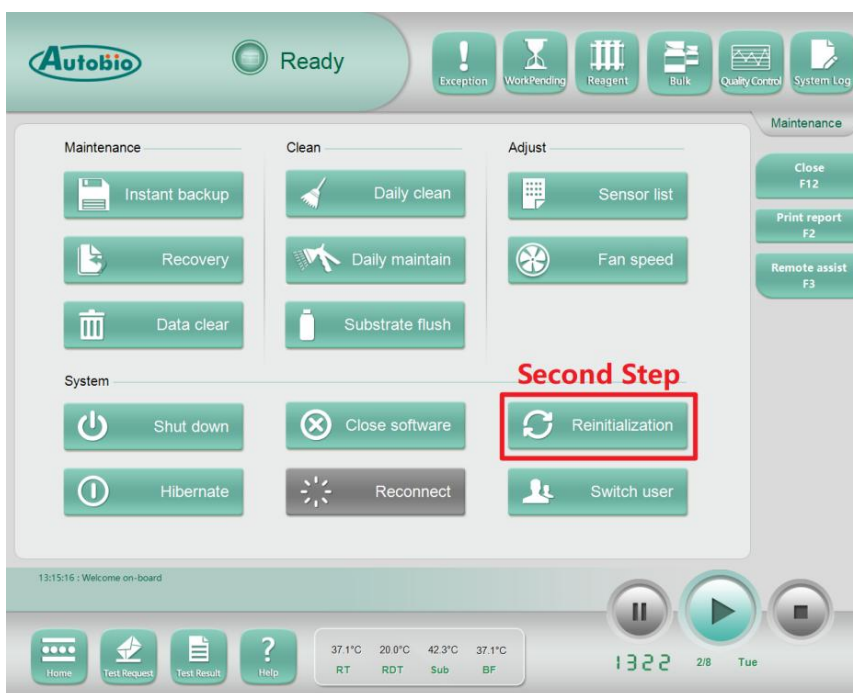
#### 4.10.1.2 Preparation for start-up

**There is no requirement for preheating time, and the preheating time can be achieved after the operation is completed according to the process.**

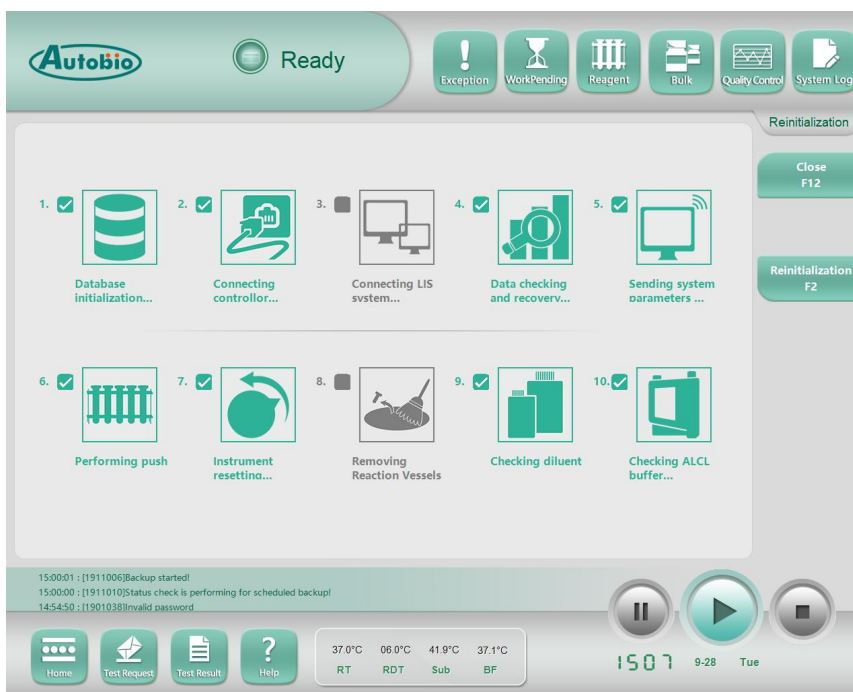
- 1) Go around to the back cover of the instrument, face the instrument, press the switch in the lower left corner of the instrument, turn on the power supply, and then the power indicator will light up.
- 2) Open the computer and start the client software.
- 3) On the main interface of the software, click "Maintenance" to enter the maintenance interface.



- 4) In the "Maintenance" interface, click "Reinitialization" to enter the reinitialization interface.



5) In the “Reinitialization” interface, click “Perform reinitialization”.



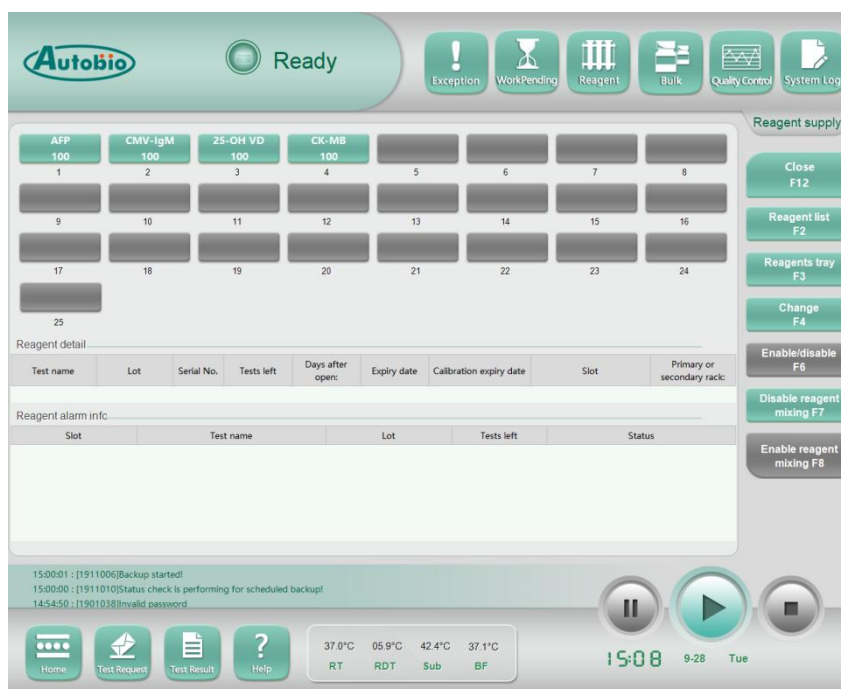
6) After the reinitialization is completed, the status of “Not Ready” on the top of the software changes to “Ready”.



### 4.10.1.3 Reagent check

1) Click the “Reagent” button on the top of the software to enter the reagent alarm interface on the instrument;





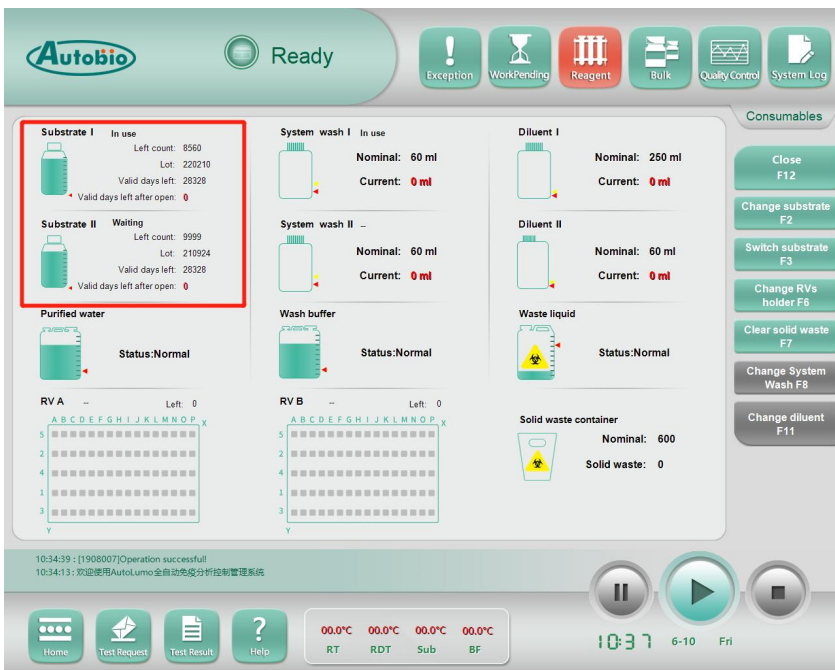
2) Check whether the remaining times of each kit on the reagent carousel are sufficient. If not, please add the reagent in time.(See Section 8.1 for details)

#### PRECAUTIONS :

- For newly added reagents, please make sure to remove the cap sticker;
- For newly added kits, it is necessary to confirm whether there are bubbles in the reagent bottles. If there are bubbles, it is necessary to use a pipette to remove them;
- Reagents should be mixed 30 minutes in advance before the experiment;
- Calibration shall be carried out before commissioning reagents of new batch number;
- Before the start of the experiment, please confirm the reagent change. Click "Change Kit" and the instrument can automatically complete the scanning confirmation of the reagent.(See Section 8.1 for details)

#### 4.10.1.4 Luminous substrate check

1) Click the "Consumables" button on the software to enter the "Bulk" interface.



2) Check whether the remaining times of the substrate meet the experimental requirements of the day. If not, please add new substrate in time. (See section 8.3.1 Replacing luminescent Substrate for operations)

**PRECAUTIONS:** Do not put substrate A and B liquid in reverse, please load according to the color of the bottle cap.



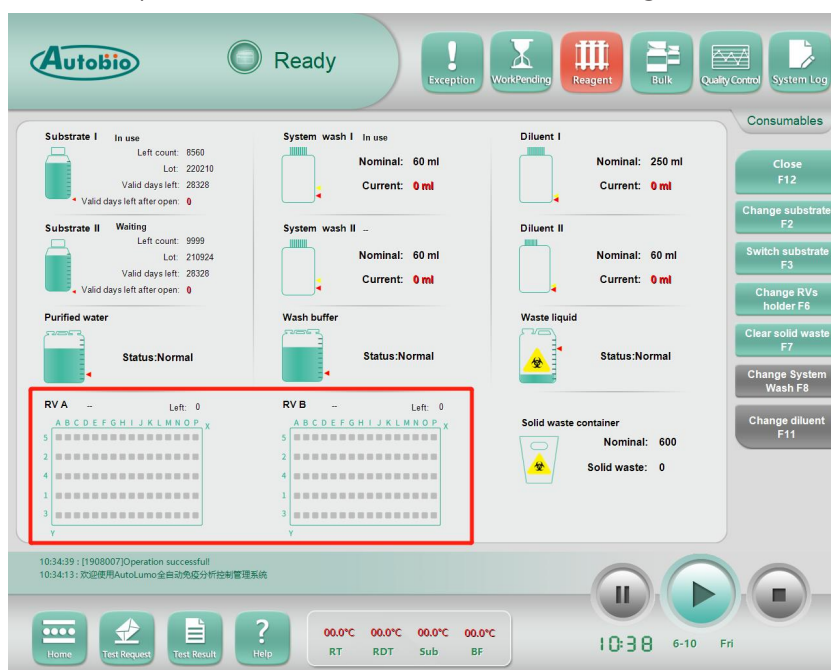
## 4.10.1.5 Consumables check

### 4.10.1.5.1 Reaction vessel check

1) Click the “Consumables” button on the software to enter the “Large-capacity Consumables” interface.



2) Check the current position in the software, as shown in the figure.



#### 4.10.1.5.2 Wash buffer and System wash check

Check whether the wash buffer and system wash is sufficient. If not enough, please add the corresponding solution in time according to preparing requirements.

PRECAUTION:

- a) If the solution is stored for a long time and not used, it should be re-prepared when the experiment starts again.
- b) If the solution has been stored for more than one week, clean the container before preparing the solution.
- c) If the experiment is suspended due to insufficient wash buffer or system wash during the experiment, please add them in time and then click the start button.

#### 4.10.1.5.3 Purified water check

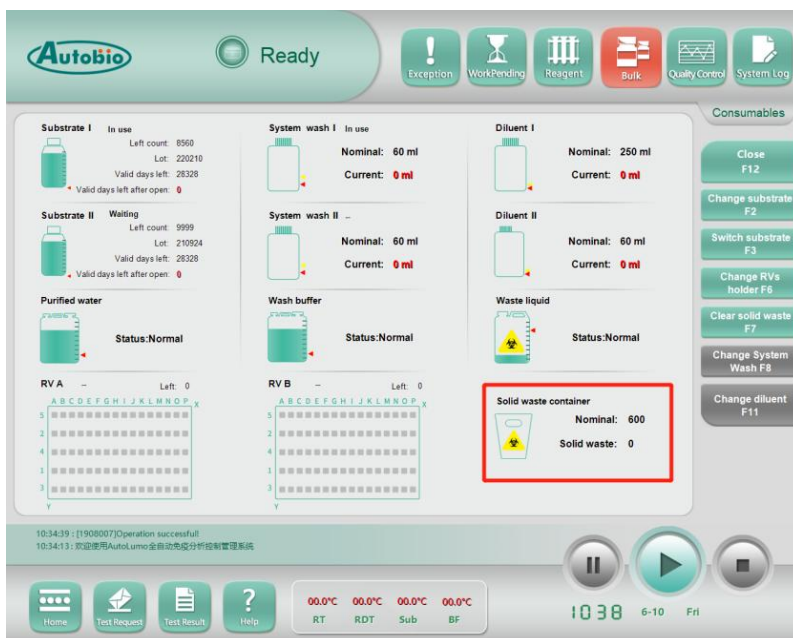
Check whether the purified water in the purified water container of the instrument is sufficient. If the purified water is insufficient, please add it in time.

#### 4.10.1.5.4 Waste liquid check

Check whether there is too much waste liquid in the waste liquid container of the instrument. If there is too much waste liquid, please clear it in time.

**PRECAUTION:** Vacuum tank and waste liquid tank of vacuum system should be cleaned every six months.

#### 4.10.1.5.5 Solid Waste check

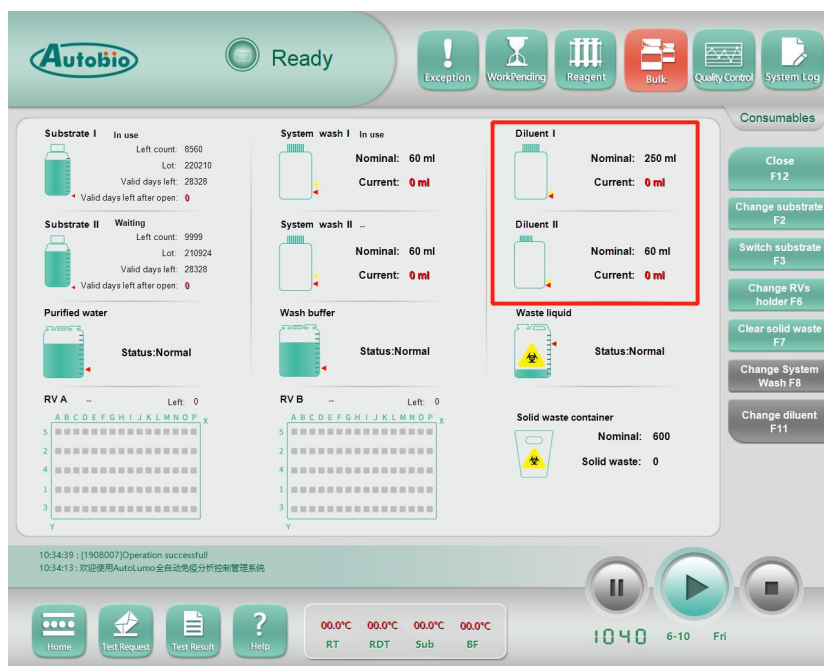




Check whether the solid waste container in the instrument is full, if it is full, please clear it in time; And click the clean up solid waste button on the interface to return to the normal state.

#### 4.10.1.5.6 Diluent check

Check whether the diluent of the instrument is sufficient, if not, please first put the diluent in the specified position, and then perform the replacement of diluent.

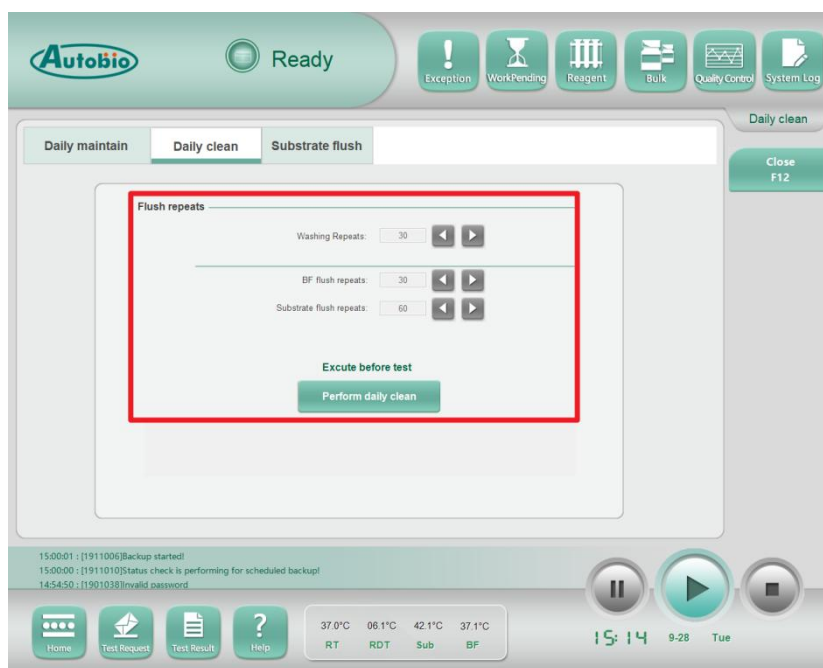


#### 4.10.1.6 Daily clean

In the software, perform "maintenance" - "daily clean" - "Perform daily clean".



Modify the daily clean times of the 3 places as required, and click “Perform daily clean”.



### 4.10.1.7 Patient test request

#### 4.10.1.7.1 Sample pretreatment

Before the experiment, the samples of the day should be fully pretreated, which should meet the following requirements:

- 1) Serum is suitable for most test items, and only serum can be used for some tests. For sample types, refer to the instructions of the kit.
- 2) Pre-treatment of samples is very important. Improper mixing, insufficient agglutination time, non-upright placement of sampling vessels or inadequate centrifugation will lead to residual fibrin in samples (visible or invisible to the naked eye), leading to abnormal test results.
- 3) Samples with severe hemolysis, severe lipids, turbidity, flocculent substances or unusable clots will result in ineffective dispersion of magnetic particles, which will seriously affect the determination results.
- 4) Avoid cross-contamination during sample operation, and use disposable pipette or sampling tips.
- 5) The accuracy of the results of the samples prepared by the static separation method cannot be guaranteed, and the samples need to be centrifuged.
- 6) Samples containing lipid stratification, blood clots, blood filaments, protein clumps or silk should be centrifuged after removing impurities.

7) The sample centrifugation process is recommended as follows:

The samples shall be placed in a warm bath at 37°C for 30 minutes (if the warm bath condition cannot be realized, the samples shall be placed at room temperature of 20-30°C, and the samples collected by the separation glue blood vessel shall be placed for no less than 30 minutes, and the samples collected by the ordinary blood vessel shall be placed for no less than 60 minutes). Then centrifugation should be at 3500-4000 rpm for at least 10 minutes.

8) Sample enhanced centrifugal processing process (applicable to high sensitivity sandwich method item) is as follows:

a) Samples collected with ordinary tubes: The samples were bathed at 37°C for 60 minutes, and the serum was transferred to a centrifuge tube and centrifuged at 10000g for 10 minutes to extract supernatant for detection.

b) Samples collected by coagulant tubes: The samples were bathed at 37°C for 30 minutes, and the serum was transferred to a centrifuge tube and centrifuged at 10000g for 10 minutes to extract supernatant for detection.

c) Samples collected by anticoagulant tubes: Transfer plasma to a centrifuge tube and centrifuge 10000g for 10 minutes to extract supernatant for detection.

The relative centrifugal force RCF value (g value) depends on the rotor speed (RPM) and the rotation radius (r, calculated in mm), and can be expressed as follows:

$$RCF(g) = 1.118 \times 10^{-5} \times (\text{rpm})^2 \times r$$

9) After centrifugation, there are lipid samples at the top of the centrifuge tube, which need to be transferred to the second sample cup or test tube. Careful operation is required to ensure that the samples are lipid-free.

10) Check whether there are bubbles in the samples. If there are bubbles, please use disposable tube or sampling device suction head to deal with them to avoid cross-contamination.

Samples that still contain blood clots, blood filaments, protein clumps or silk after centrifugation should be removed and centrifuged again.



#### **CAUTION:**

If the samples are not processed in strict accordance with the pretreatment requirements, Autobio will not take any responsibility for the abnormal sample results.

#### **4.10.1.7.2 Edit the sample**

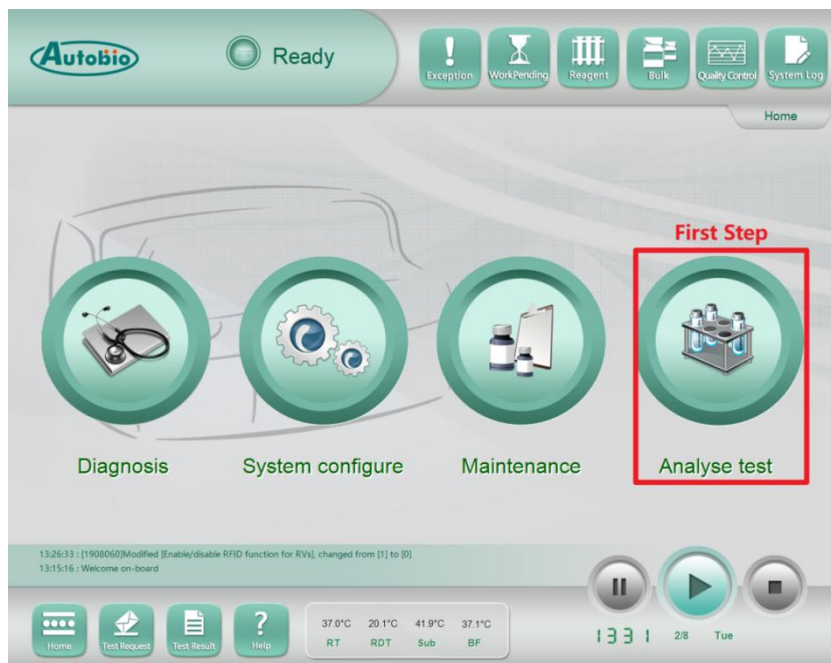
##### **4.10.1.7.2.1 Enter the test request interface**

There are two methods

Method 1: click the "Test Request" at the bottom left of the software to enter the "Test Request" interface directly.



Method 2: On the main interface of the software, click "Analyse test" -- "Patient Test Request" to enter the "Test Request" interface.





#### 4.10.1.7.2.2 Edit sample information (see “Part 3 Patient Samples” for details)

- 1) Sample rack bar code “RDO2” can be input by scanner or manually;
- 2) Input the sample no. in the corresponding position of “Sample Number”;

Click the item to be added, and the item will be displayed in the “Test Request” area on the left, indicating that the item is added successfully. If it is added by mistake, select the item in the “Test Request” area (gray after selected) and click “Delete Request”.



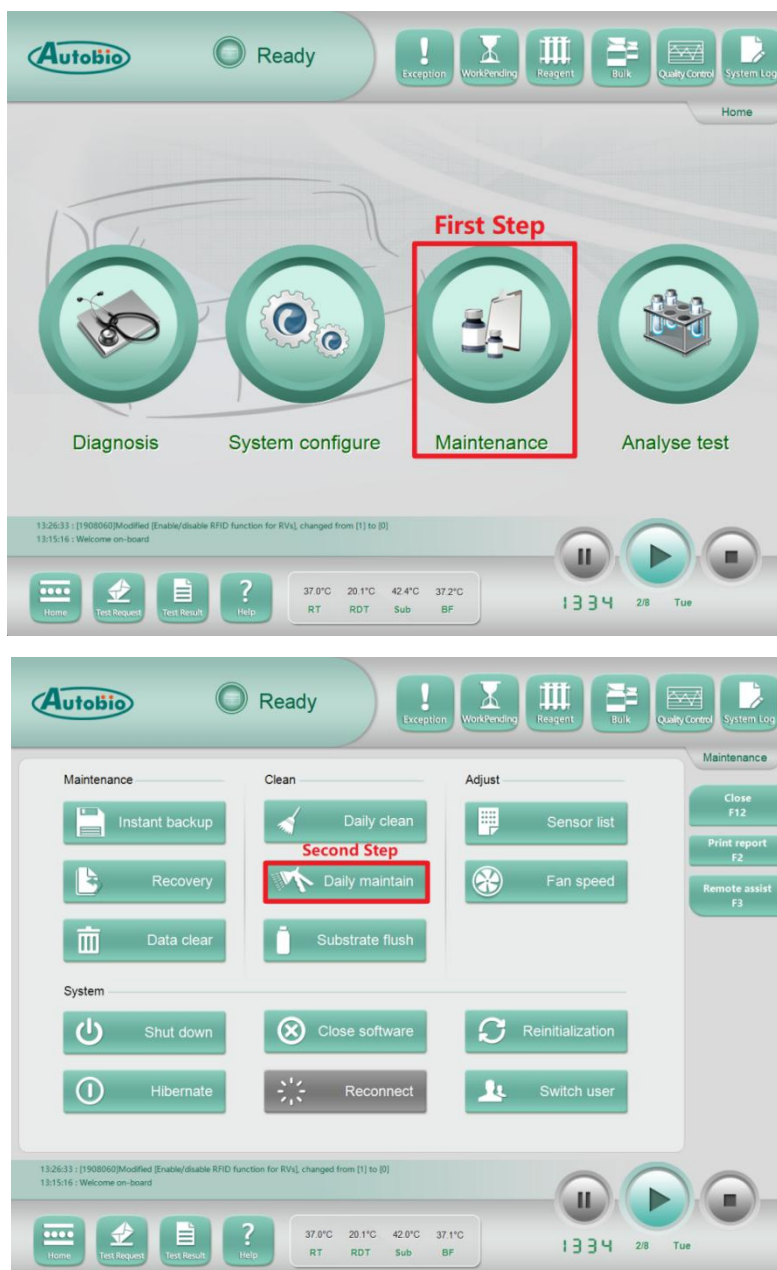


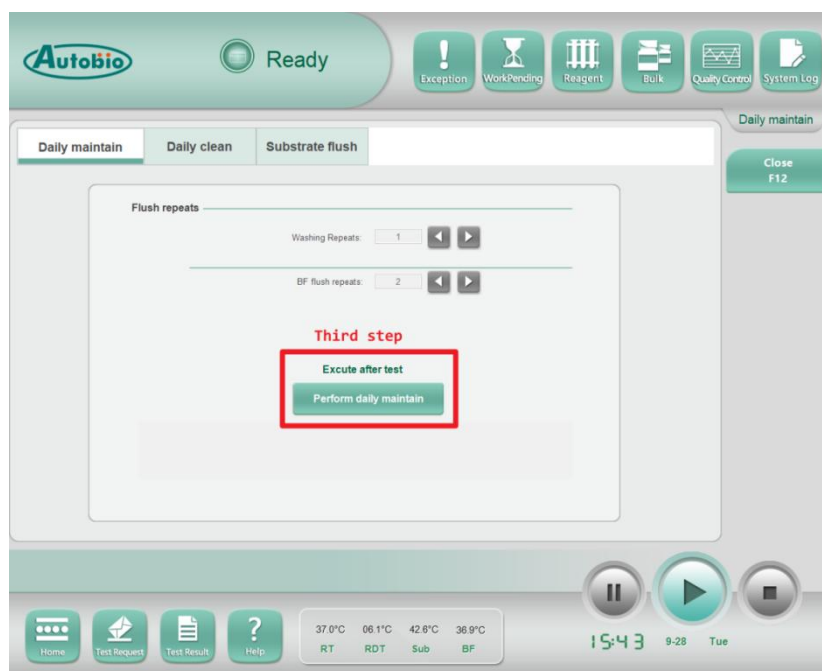
### 4.10.1.7.2.3 Start the experiment

After the sample editing is completed, put the sample rack into the loading device of the sample rack correctly, close the central door, and click the "Start" button at the bottom right of the software to start the experiment.

### 4.10.1.8 Daily maintain

In the main interface of the software, click "Maintenance" -- "Daily maintain" -- "Perform daily maintain".





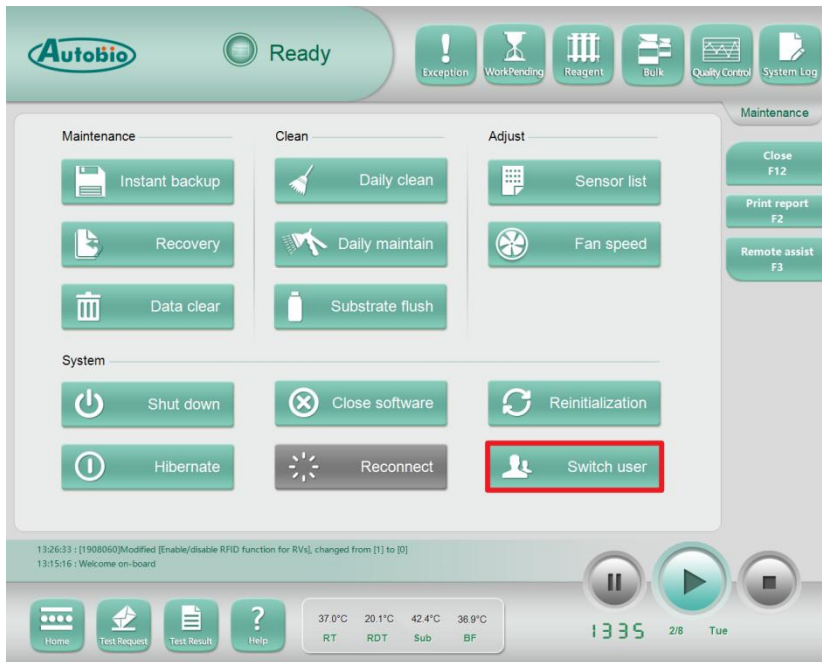
#### 4.10.1.9 Shut down the instrument

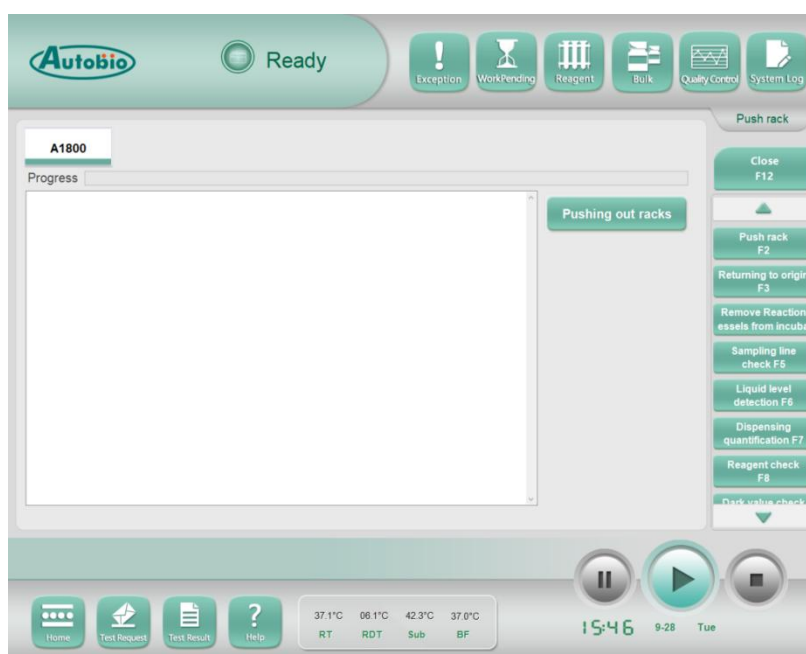
After the end of the experiment and the daily maintain, the instrument should be turned off (the power switch of the instrument is located at the lower left of the instrument), and the computer should be turned off.

### 4.11 System diagnosis

On the main interface of the system, click the "Diagnose" button to enter the diagnosis interface, which helps you check the faults in the system. The following table describes each diagnostic item. Please read it in detail. You can access the diagnosis interface only with the permission of [Administrator] or [Maintainer]. To facilitate your operations, switch roles in advance.





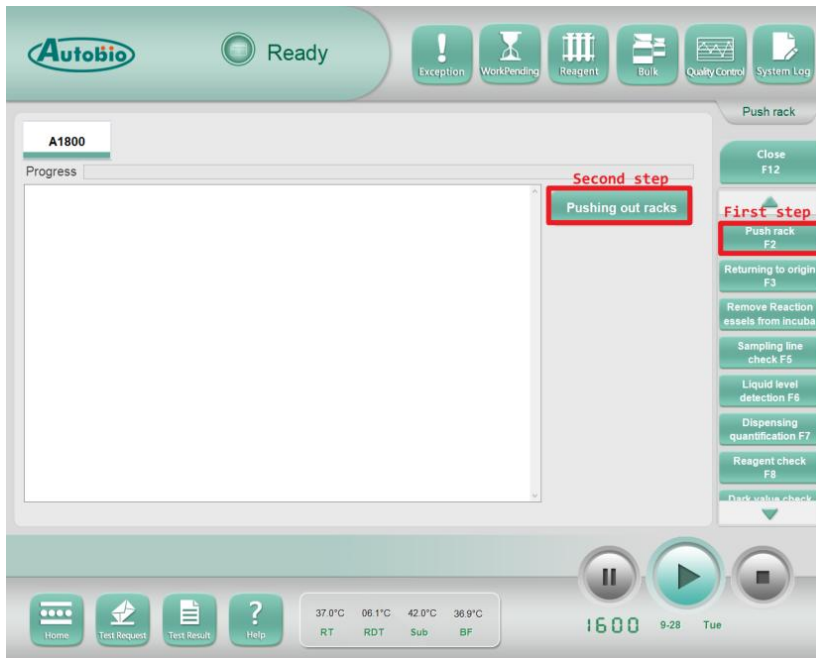


Control button	Description
Close this window	Return directly to the main interface
Push sample rack	Push unrepositioned sample rack
Origin return	Restore all mechanical components to their initial positions
Clear the incubation tray	Remove all reaction vessels from the reaction tray and pretreatment tray
Sampling line check	Determine the bar code scanning function of the sample rack by performing sampling line check, and determine whether the sensor is normal by the position of the sample cup; Continuous reading of the bar codes of the sample rack and reagent rack is carried out by starting continuous reading of bar codes
Liquid level detection	Determine whether the corresponding liquid level detection function is normal
Quantitative test	The difference between the test value and the set value is compared by the balance measurement, so as to judge the injection accuracy
Reagent check	Read reagent bar code
Dark value check	Dark value check is used to determine whether the light metering

	unit seal is intact
Light source detection	By testing the substance in the reaction vessel, to judge whether PMT metering is normal or not
Pressure testing	It's to check whether sample probe is blocked.
Autobio light source test	Determine whether the measurement value of the instrument meets the requirements
Blending test	The mixing test is used to judge whether the mixing motor is normal and whether the mixing strength is appropriate
Liquid Level detection calibration	Obtain the threshold for liquid level detection
Water emptying test	To water or empty the instrument
Pressure detection calibration	Obtain the pressure thresholds of different amounts of fluid extracted by the probe
Substrate decrystallization	Soak the substrate probe to prevent crystallization of the substrate probe
Print report	Click print test report

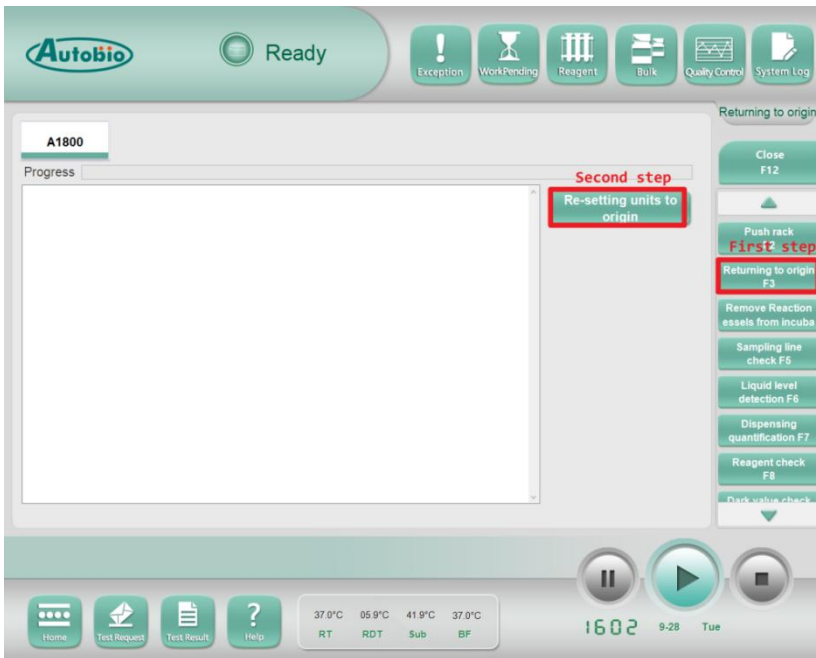
#### 4.11.1 Push Sample Rack

As shown in the figure:

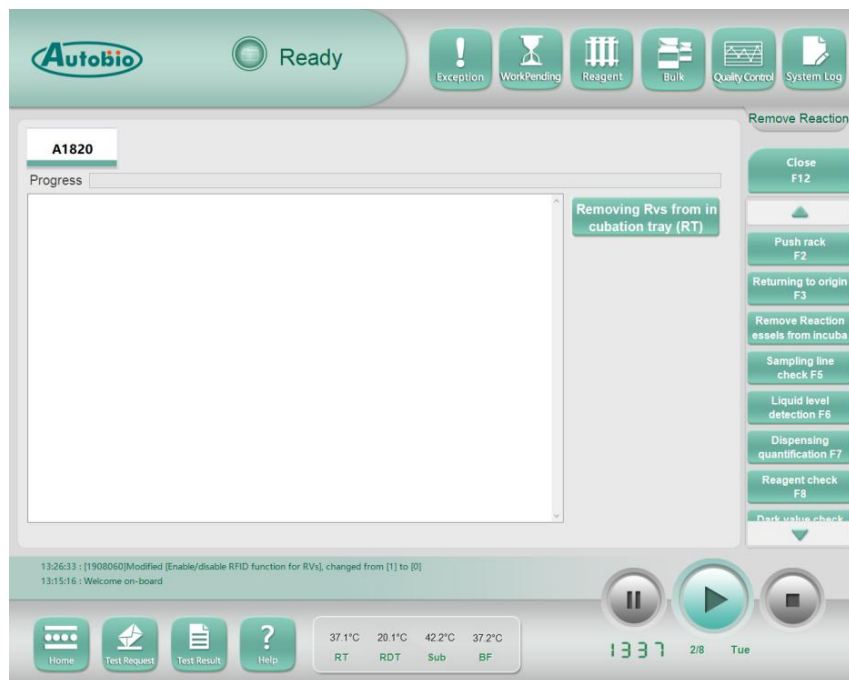
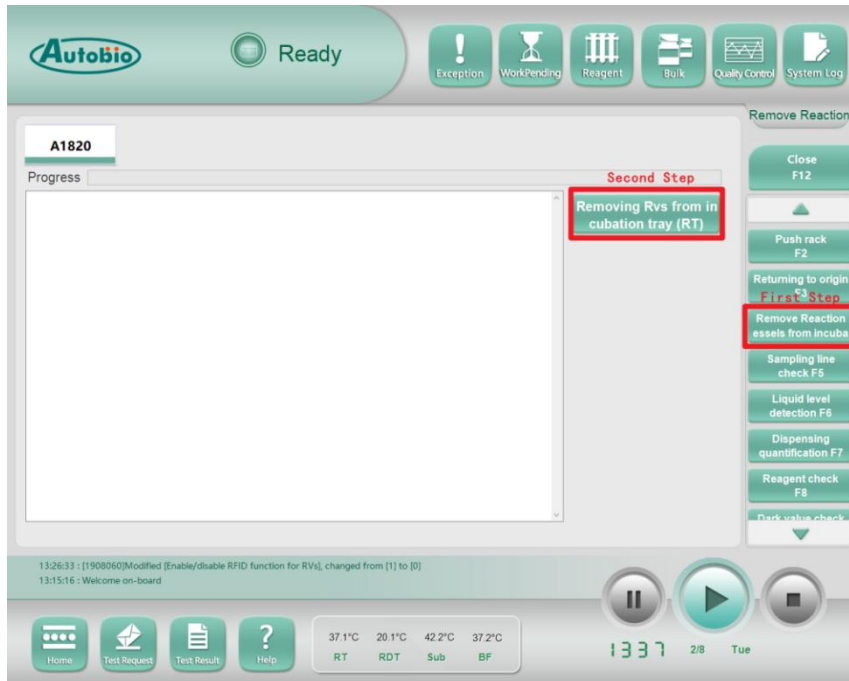


### 4.11.2 Origin Return

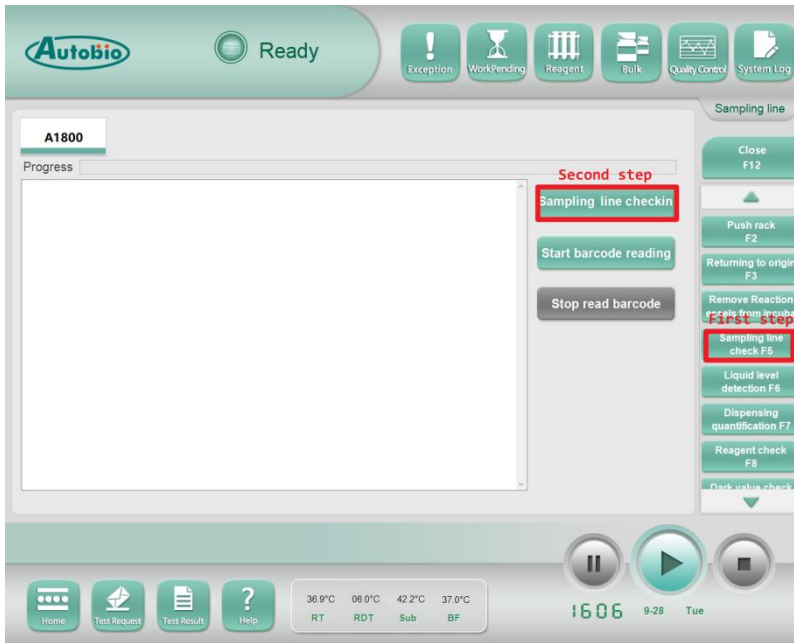
As shown in the figure:



### 4.11.3 Clear the Incubation Tray

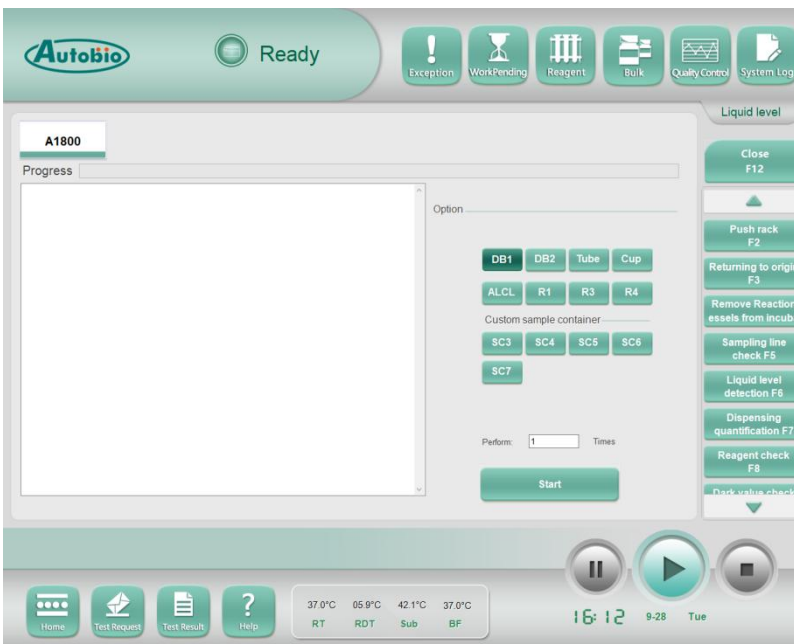


### 4.11.4 Sampling Line Check



- 1) The sampling line can be checked according to the steps shown in the figure.
- 2) Manually push the sample rack to the position of scanning and click “Start continuous barcode reading” to continuously read the barcode of the sample rack and reagent rack.

### 4.11.5 Liquid Level Detection

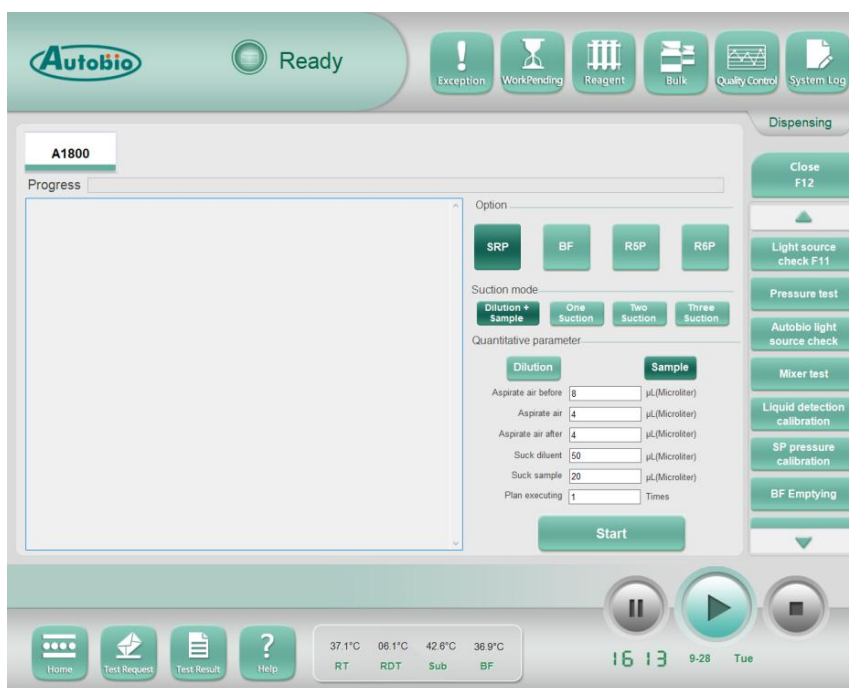


- 1) Enter the liquid level detection interface and select the position of the sampling probe.
- 2) Enter the number of times and click the "Start" button.

Please carefully check the corresponding position of the sampling probe. In the case of liquid level detection failure, the wrong choice may increase the risk of sampling probe crashing.

### 4.11.6 Quantitative Test

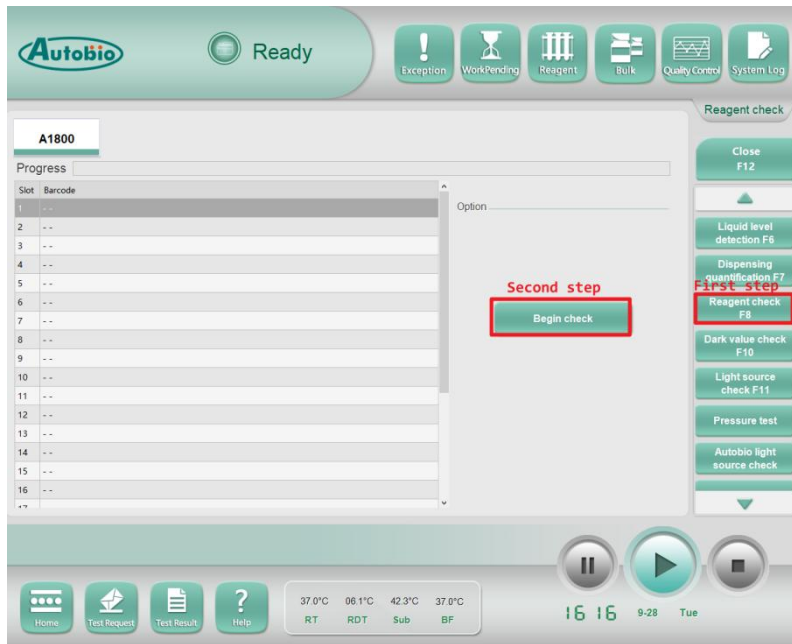
As shown in the figure:



- 1) Enter the quantitative test interface, select the pump type;
- 2) Select the suction mode;
- 3) If the suction mode is selected, select the suction fluid type in the quantitative parameters and set the corresponding parameters and execution times;
- 4) If the quantifying of substrate and BF wash buffer is performed, please put the reaction vessel into the upper left corner of the incubation tray, in which 1 reaction vessel is needed for substrate and 5 for BF wash buffer; Please place the reaction vessel in SS1 position if the quantitative test of sampling probe is performed.
- 5) Click the "Start " button to execute.

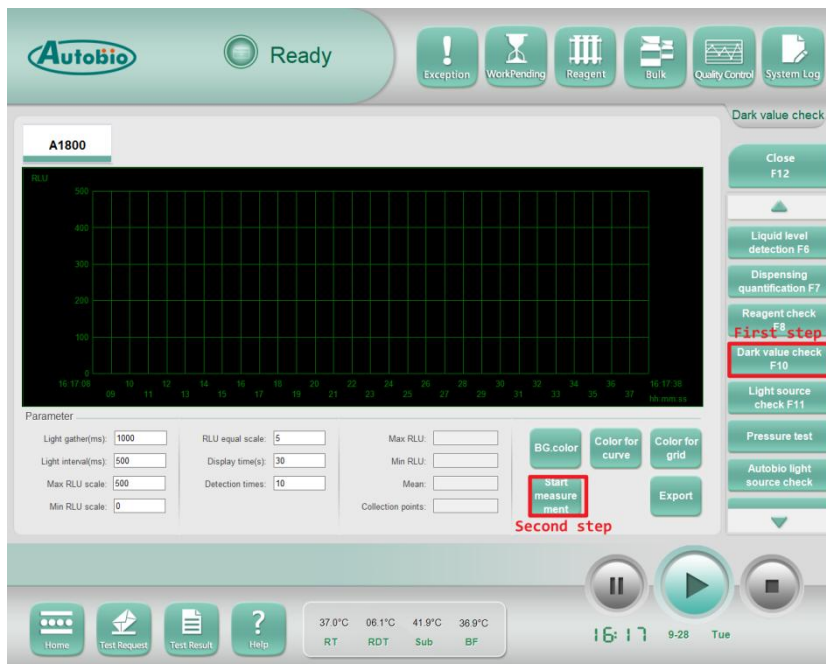
### 4.11.7 Reagent Check

As shown in the figure:



- 1) Enter the reagent check interface;
- 2) Click “Begin Check”;
- 3) Please confirm that the reagent has been placed in the corresponding position of the reagent carousel before starting the check.

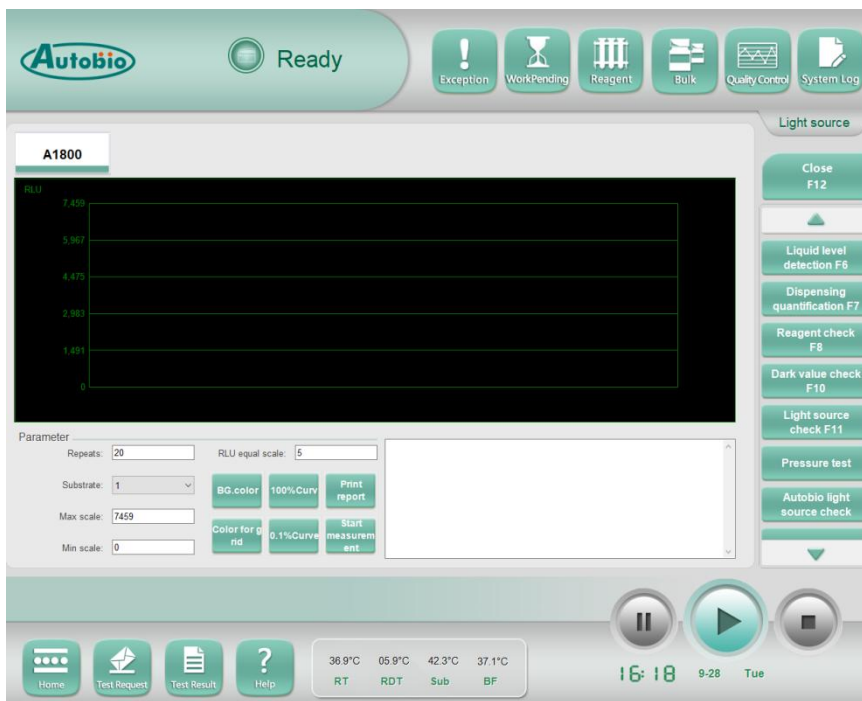
#### 4.11.8 Dark Value Detection





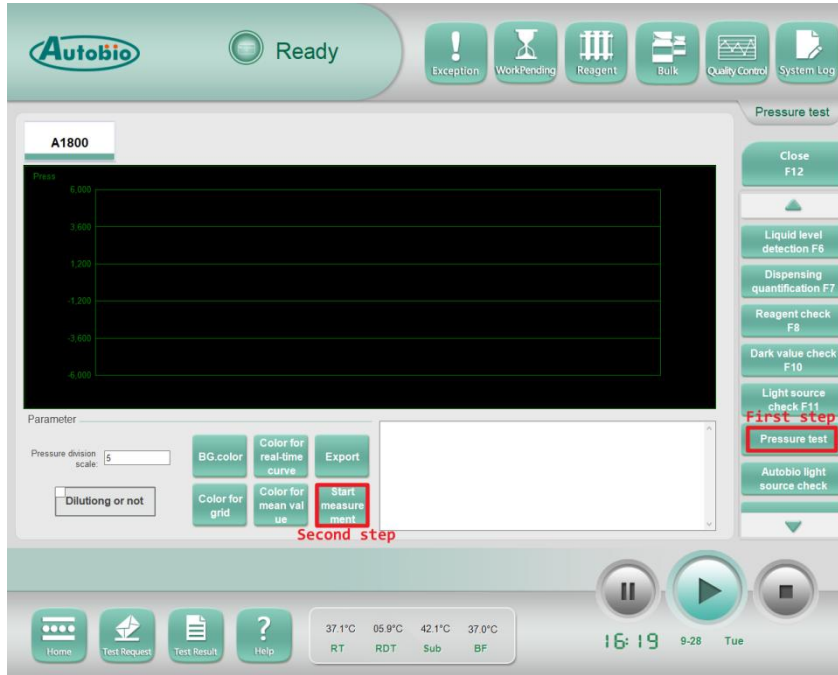
- 1) After entering the dark value detection interface, set each parameter value;
- 2) Set background, curve and grid color according to requirements;
- 3) Click “Start Measurement”. After metering, click “Export” to export the data;
- 4) Before the dark value test, please confirm that the cover of the incubation tray is completely closed.

### 4.11.9 Light Source Detection



- 1) After entering the light source detection interface, set each parameter and adjust the color;
- 2) After setting, click “Start Measurement”.

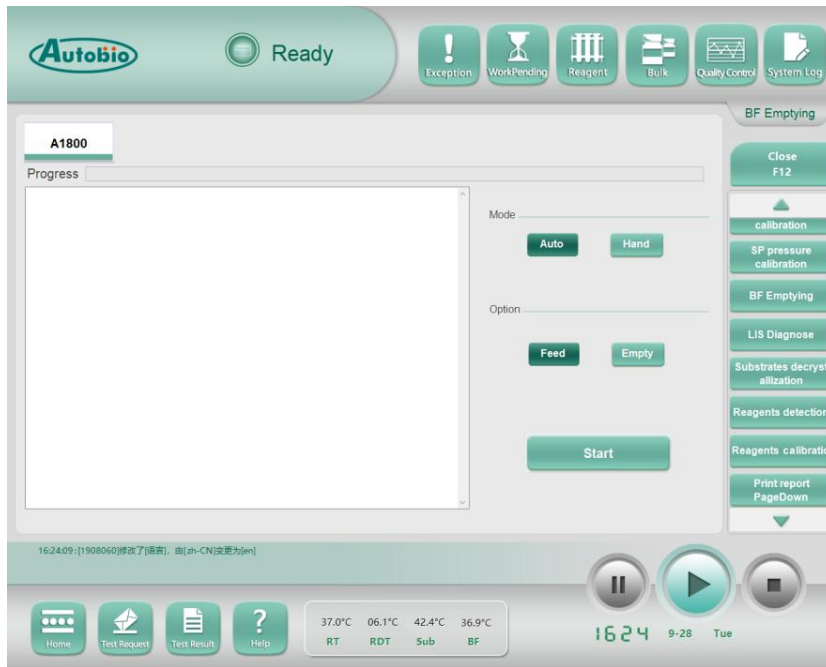
### 4.11.10 Pressure Test



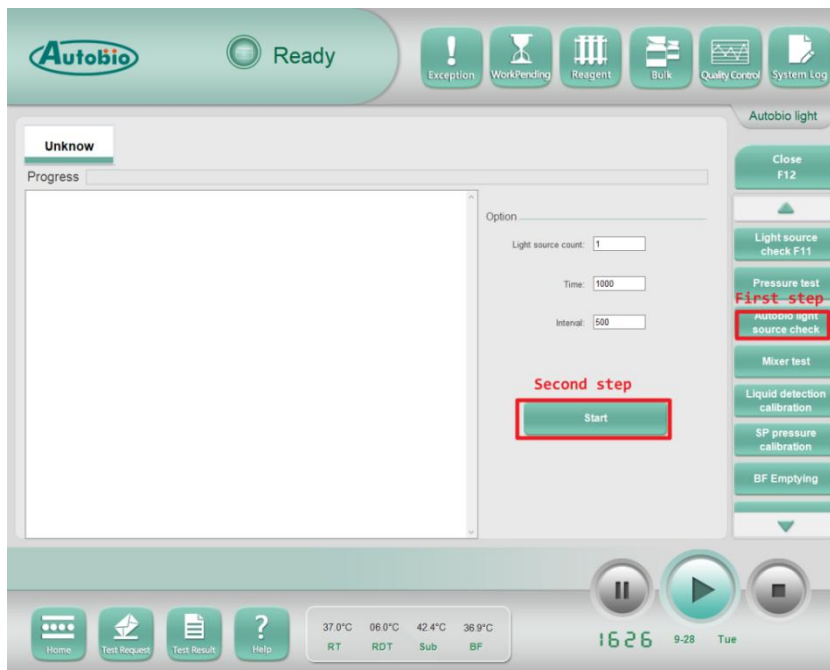
- 1) After entering the pressure test interface, the input pressure value is equally graduated;
- 2) Set the color as required;
- 3) Click “Start Measurement” and click “Export” to export the data after the test.

### 4.11.11 BF Emptying

- 1) After entering the BF Emptying interface, select the mode as shown in the following figure, Auto or hand; If Hand is selected, strictly follow the instructions on the interface.
- 2) Select the test type of BF emptying test: Feed, Empty;
- 3) Click the “Start” button in the interface.



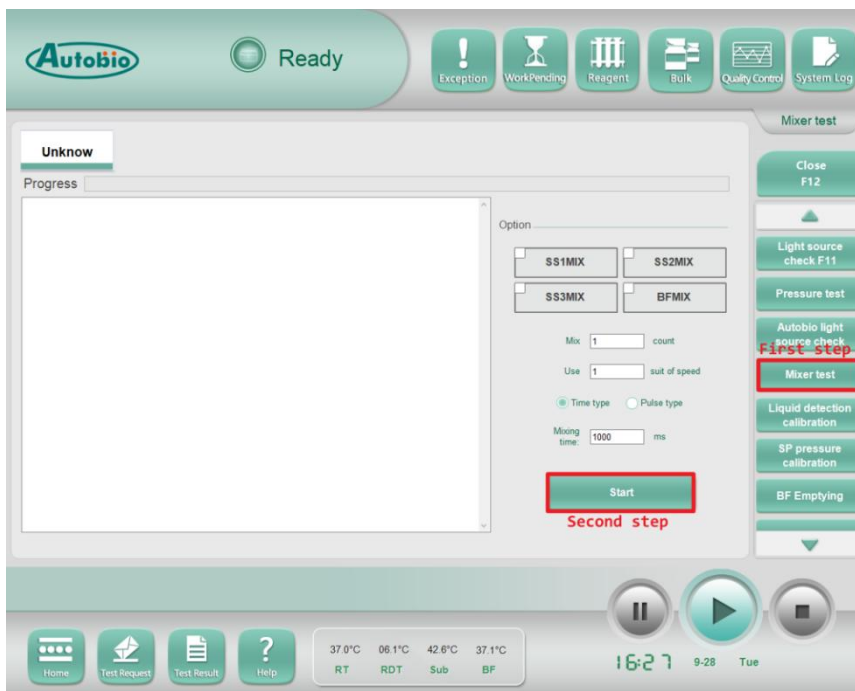
#### 4.11.12 Autobio Light Source Test



- 1) After entering the Autobio light source test interface;
- 2) Input relevant parameters as required;

3) Click the "start" button on the interface to perform the operation.

### 4.11.13 Mixer test

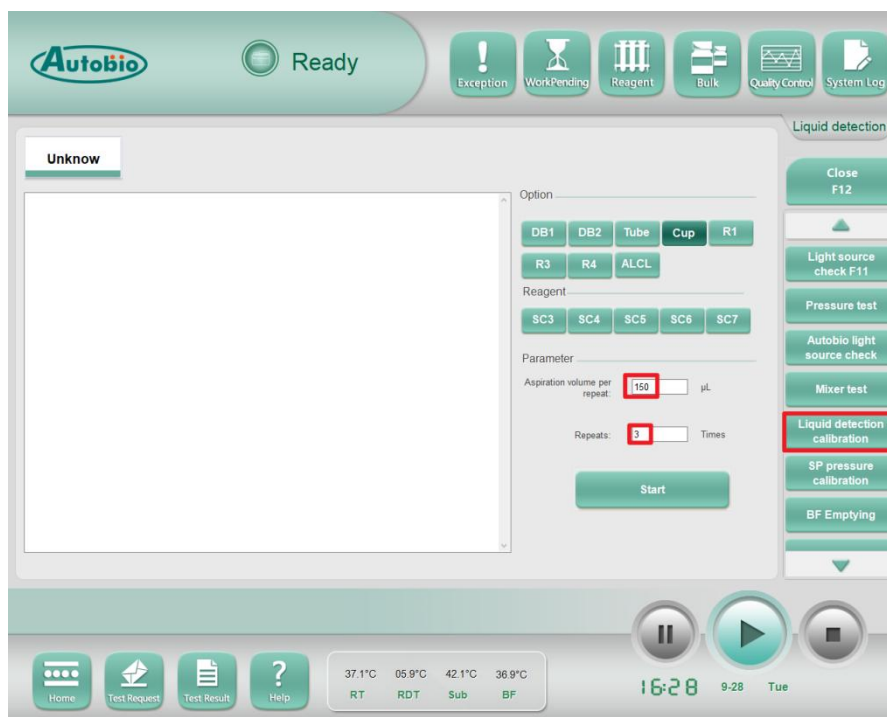


1) After entering the interface, put the reaction vessel in the corresponding position after blending;

2) Enter the execution times;

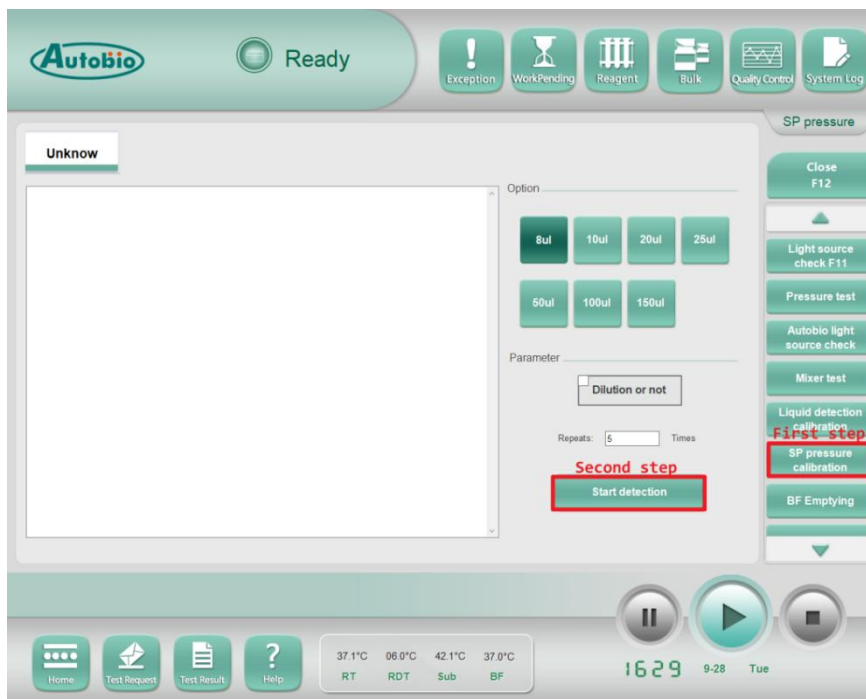
3) Click the "Start" button in the interface to perform the operation.

#### 4.11.14 Liquid Level detection calibration



- 1) After entering the interface, select options and set parameters as required;
- 2) Place clean and dry reagent bottles at R1 position, R3 position and R4 position of reagent rack 1, and then place these in reagent tray 1.
- 3) Place the clean and dry sample cup or tube in position 1 of the sample rack, and place the sample rack in slot 1 of the sample tray;
- 4) Put 20ml purified water in large dilution bottles and 7mL purified water in small dilution bottles and alkali washed bottles;
- 5) Click the “Start” button on the interface to perform the operation.

## 4.11.15 Pressure Detection Calibration



### 1) Preparation

- a) Two empty sample containers (Cup, Tube) of the same specification;
- b) One dilution bottle of any size;
- c) 1 sample rack;
- d) Some purified water.

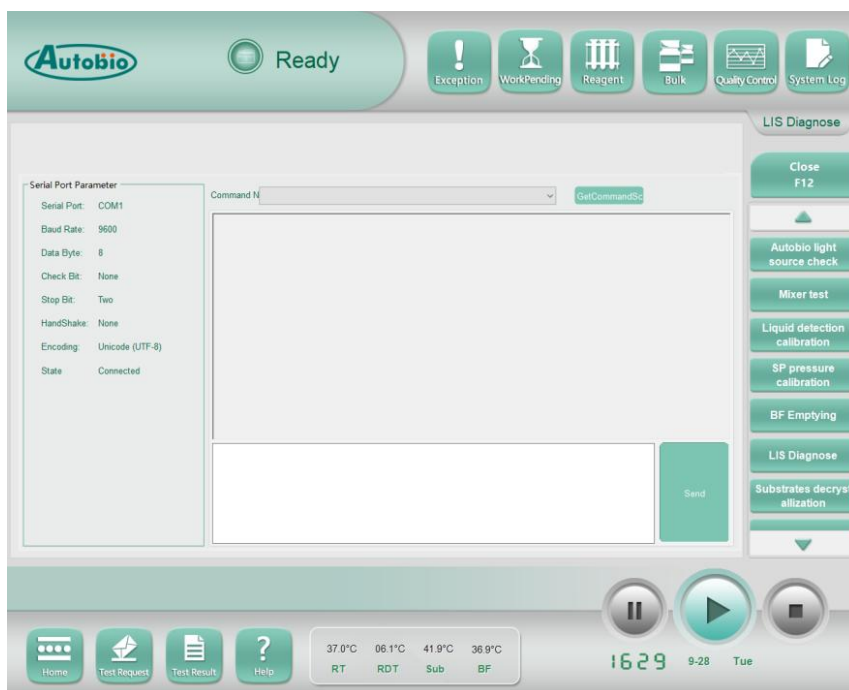
### 2) Operation procedure

- a) Pour an appropriate amount of purified water (more than 1.5ml is appropriate) into one of the sample cups and place it in position 2 of the sample rack. Place the empty sample cup in position 1;
- b) Pour some purified water (more than 20ml is appropriate) into the dilution bottle and place it at the dilution position;
- c) Place the sample rack in slot 1 of the sample tray
- d) Parameter setting (more than 3 times is required), perform the calibration of 10ul, 20ul, 50ul, 100ul and 150ul non-dilution pressure test and calibration of 10ul, 20ul and 50ul dilution pressure test respectively;

**NOTE:**

During the calibration process, sufficient amount of purified water should be ensured in the No.2 sample cup; The pressure value displayed on the interface should be around 7000 (the first pressure value is 0). If the deviation is obvious, contact our engineers to confirm the reason.

e) End the pressure calibration, remove the sample rack and dilution bottle, and the calibration is finished.

**4.11.16 LIS Connection Test**

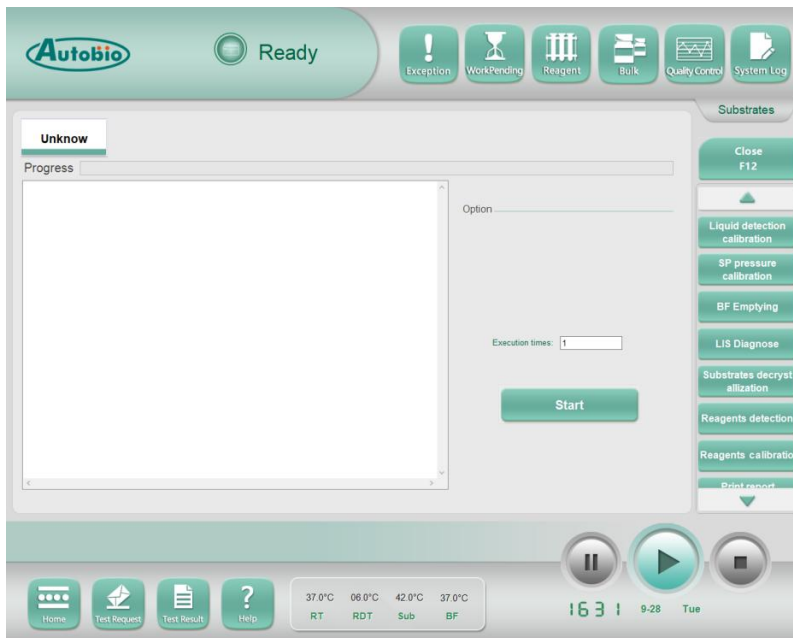
1) Enter the “Main Interface”, click “Diagnosis”, and select “LIS Connection Test” from “Diagnosis”;

2) Select the instruction template from the left drop-down box of [Generate instruction script];

3) Click [Send] on the interface to view the information returned by the LIS system;

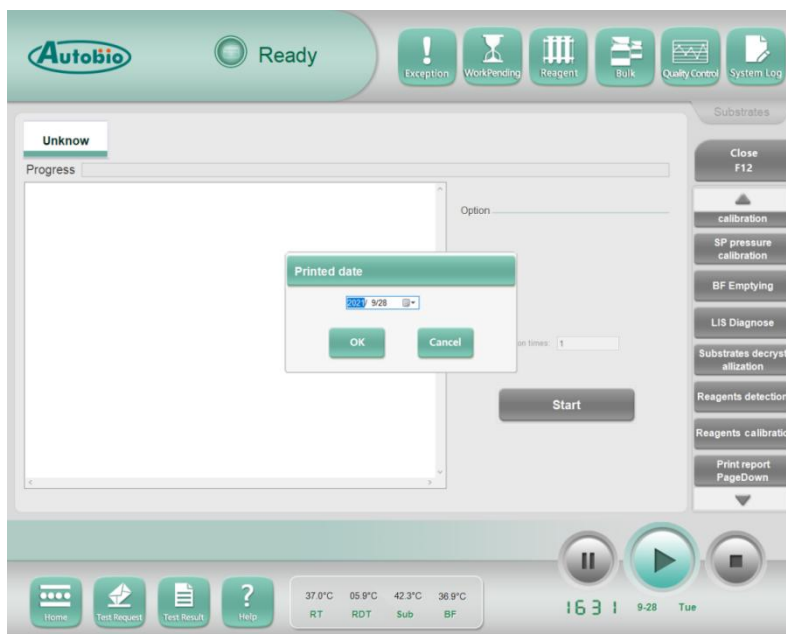
Note: You can also directly input the format of LIS instruction to be sent in the input box; Use this function in conjunction with LIS connection settings.

### 4.11.17 Substrate De-crystallization



- 1) Enter the “Main Interface”, click “Diagnosis”, and select “Substrate Decrystallization” from “Diagnosis”;
- 2) Set the execution times;
- 3) Click “Start” on the interface.

### 4.11.18 Print Report





- 1) After entering the interface, select the time;
- 2) Click “OK” on the interface, preview the report you want to print, and you can print it.

**CAUTION:**

- 1) Do not perform any operation or function not described in the manual. Failure to do so may result in incorrect test results, serious or fatal personal injury or material loss.
- 2) Although the instrument is equipped with a blood clot detection system, the user is not allowed to intentionally insert a blood clot into the instrument sample tube without Autobio’s authorization. The user is responsible for any improper use related to the system defaults.
- 3) The incorrect use, adjustment or non-standard operation of the barcode scanner may lead to the dangerous emission of strong light radiation
- 4) Only trained and authorized users can access the system.
- 5) The system may encounter risks of unauthorized access, resulting in possible data loss, damage or unauthorized distribution.
- 6) If any fault occurs in the diagnosis system, please contact Autobio .

## 5 Maintenance and Service

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### CAUTION:

#### Statement

Prior to commencing any maintenance or cleaning work, switch off the instrument and pull the mains plug.

It is essential that the AutoLumo A1800 is maintained in accordance with the maintenance plan and procedures described in the operating manual in order to operate the system correctly. Due maintenance tasks and the required procedure should be carried out by users according to given scheduling of the system.

### 5.1 Safety and Prompts

Maintenance activity may involve some risks, which can refer to the chapter 1.1.5-1.1.10 for detailed description. Attention should be paid to the following:

- 1) Improper maintenance actions can result in serious personal injuries and materials damage.
- 2) Unapproved or inaccurately performed maintenance actions can result in physical injury or deterioration in the state of health.
- 3) Replacement of instruments, packing materials and all components must be handled in accordance with applicable local and national regulations, laws and laboratory procedures.
- 4) If the system cannot be separated from the mains supply when performing required maintenance works, additional precautions must be taken to avoid serious injury with lethal consequences due to electrocution or mechanical injury by the system.



### CAUTION:

Observe strictly the applicable national and local provisions, legislation and laboratory procedures during the maintenance explicitly required.

### 5.2 Maintenance

Refer to 4.9 Maintenance Contents. The service personnel of the company shall explain, train and check the actual operation of the daily maintenance work required by the users according to the contents of the Service Manual.

Also please check

- 1) whether the power cord is damaged before use.

2) Please clean the dust on the plug regularly to avoid danger.

### **5.3 Attached Accessories and Consumables**

Refer to “4.9.7 Parts and Consumables Replacement/Maintenance”, and the service personnel of the company will explain and train according to the Packing List and Service Manual.

### **5.4 Wearing Parts Replace**

Refer to “4.9.8 List of Wearing Parts and Replacement/Maintenance”, and the service personnel of the Company shall replace and maintain the parts according to the “Service Manual”. Users do not need to replace the parts by themselves.

## 6 Trouble shooting

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The debugging and reophe instrument must be carried out by manufacturer or agent. If it is involved in the inspection of the internal moving parts of the instrument, the instrument should be powered off. Safety protection must be taken during the debugging process to avoid serious casualties caused by electric shock or injury (such as contusion, cut, etc.). If necessary, maintenance personnel may block some sensor functions for maintenance. Please pay attention to safety and restore the safety protection sensor after troubleshooting. Refer to the Service Manual for details. Do not use organic solvents, as reagent containers and hoses may be severely damaged or unservicable by organic solvents.



### CAUTION:

Unapproved or improperly performed maintenance operations may result in serious personal injury and material damage.

The following solutions are for simple errors. Please contact manufacturer or agent if there are any other problems or errors not indicated in the following table.

#### Fault I-----

##### Fault description:

The reaction vessel is insufficient, please check; The number of available reaction vessels is insufficient. Please scan and update the number of reaction vessels in time

##### Fault analysis:

1. Insufficient supply of reaction vessels on the reaction vessel holder.
2. The available reaction vessel holder is insufficient, so users need to manually scan the barcode of the reaction vessel and add the reaction vessel holder.

##### Treatment method:

Add the reaction vessel holder and click Run.

#### Fault II-----

##### Fault description:

Click on the Run button, a message is displayed indicating that the test cannot be started

##### Fault analysis:

- a) The central door is not closed, the state of the central door sensor is not correct, and the sample cannot be loaded;
- b) The cover of the reagent carousel is not closed;
- c) Clamshell is not closed;
- d) Incubation and refrigeration temperature is not up to standard;
- e) Reagent blending time after startup is not up to standard;
- f) Lack of reagents or consumables;
- g) The liquid in the liquid container is insufficient or the waste container is full;

- h) Sensor failure;
- i) Independent cooling function is on, the instrument is not online or the instrument is not initialized.

**Treatment method:**

- a) Check the warning status, perform corresponding operations, and confirm that the instruments start sampling;
- b) If the above problems are not solved, contact the manufacturer or agent.

**Fault III**-----**Fault description:**

Sampling line is jammed.

**Fault analysis:**

Sampling line sensor is mistakenly triggered.

**Treatment method:**

Wait for the end of the running experiment, re-initialize the instrument. Put the unperformed experiment back in, and click "Run" to start the experiment.  
Contact the manufacturer or agent;

**Fault IV**-----**Fault description:**

The instrument clamshell is open, causing the emergency stop.

**Fault analysis:**

The front cover of the instrument was opened.

**Treatment method:**

- a) Confirm whether there is a problem with the location of sample/reagent addition unit. If there is a problem, power off the instrument, open the large clamshell, manually adjust the probe to the initialization position, and then power on;
- b) To re-initialize the instrument, click "Clean the incubation tray", re-edit the sample, and click "Run" to start the experiment.

**Fault V**-----**Fault description:**

Empty suction occurred when reagent was added.

**Fault analysis:**

New reagent was put in without performing the liquid level detection.

**Treatment method:**

When the new reagent is put in, the liquid level shall be detected according to the normal process, and the database shall be saved.

**Fault VI**-----**Fault description:**

The reaction vessel is not properly placed in the gripper. Check the reaction vessel aligner or gripper for abnormalities.

**Fault analysis:**

Reaction vessel supply or gripper is abnormal.

**Treatment method:**

Check whether the arrangement of reaction vessels on the rack is consistent with that on the software interface. If not, please update the consumables in time, and click "Reinitialize".

**Fault VII**-----

**Fault description:**

The instrument has not been initialized, so the test cannot be started.

**Fault analysis:**

Start the experiment while the instrument is not ready.

**Treatment method:**

Re-initialize the instrument and click "Run" to start the experiment.

**Fault VIII**-----

**Fault description:**

This test is about to end, and the sample management unit will stop sampling.

**Fault analysis:**

The on-going experiment is about to end. No further injection is allowed.

**Treatment method:**

After the end of the experiment, click the "Run" button to continue the experiment.

## 7 Transport and Storage

### 7.1 Transport Requirements

Transportation conditions should meet the storage requirements of temperature and humidity. The temperature should be between - 40 °C and 55 °C , and relative humidity no more than 90 % RH. Instrument in the transportation and handling process should be waterproof and moisture-proof, prevent violent vibration, tilt and extrusion. When handling, loading or unloading, follow the instructions of professional engineers from Autobio or follow the following methods. Unpacked transportation is prohibited. Before transportation, please check the integrity of the instrument packaging, anti-vibration and tilt indicator. At the same time, please check whether the direction of the "upward" sign of the instrument packaging is correct. After the completion of loading, please fix the outer packing of the instrument on the inner wall of the trunk with the binding belt and the pincher. After transportation, please check the packing and the status of anti-vibration and tilt indicator. The following figure shows the no problem state of the indicator and the normal direction of the upward sign.



Tilt indicator (no problem state)    Anti-vibration indicator (no problem state)



Package symbols (Matters needing attention)

**NOTE:**

- 1) The product can be unpacked and installed only by authorized service personnel.
- 2) Please verify that the delivery is complete on receipt of the AutoLumo A1800 and check for possible transport damage. If the delivery was incomplete or the device was damaged during transport, please contact Autobio.

## 7.2 Storage Requirements

Packaged analyzer should be stored in a non-open place or indoor, which should be  $-40\text{ }^{\circ}\text{C}$  ~  $55\text{ }^{\circ}\text{C}$ , relative humidity  $\leq 90\%$ , clean, neat, no water, no weeds, no chemicals, no corrosive gas, good ventilation, no other pollution sources, no strong direct sunlight and sheltered from rain.

In addition to the above temperature and humidity requirements, unpacked instruments should also be dust-proof and waterproof, such as wrapping them with stretch film or wrapped in plastic bags.

The instrument and the ground, the wall, the ceiling, the radiator should have the corresponding spacing: The distance between the instrument and the wall, the ceiling should be not less than 30 cm, the distance between the radiator or heating tube should be not less than 30 cm, and the distance between the ground should be not less than 10 cm.

If the instrument is stored for a long time, the liquid circuit shall be cleaned and emptied, and the relevant peripheral accessories shall be preserved and packaged, registered and sealed. If the instrument has been stored for more than three months, please contact the service engineer authorized by Autobio to re-evaluate the device performance before reuse.



## 8 Relevant Description of Cybersecurity

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The AutoLumo A1800 software is intended to be used in a controlled environment. Access to the system is allowed only to trained and authorized users. Nevertheless, usage of the system may undergo the risk of unauthorized access, leading to the data loss, corruption or unauthorized distribution.

Relevant description of cybersecurity is as follows:

### 1 ) Operating Environment

#### a ) Hardware Configuration

For hardware configuration requirements, please refer to section 2.5.5.3.

#### b ) Software Environment

Operating system: Win 10 or above

Running environment : Net framework3.5

Database: Microsoft Sql Server 2012 or above

#### c ) Network Condition

TCP/IP protocol

### 2 ) Security Software(operating system built-in firewall )

#### a) Data and Equipment (system) Interface

b) The computer communicates with the analyzer through RJ45 network port and the communication protocol is TCP/IP. The data is stored in the SQL Server database.

#### User Access Mechanism

Access control: Any unauthorized external access is not permitted.

Access record: The system provides user access records and operation logs for review and

tracing.

Permission control: The system has function operation permission control. Check the software system Settings according to the status and permission management of maintainer, administrator, and operator to ensure software and data security.

Security Software Update

Update the firewall and parameter settings through the remote service platform.

## Appendix 1- Serious Flags

Flag	Description	Correct operation
CCR	<p>The result cannot be calculated for the following reasons:</p> <ul style="list-style-type: none"> <li>• The derived result calculation formula contains a certain test that cannot produce a result.</li> <li>• Another error caused the system to fail to calculate the results.</li> </ul>	<ol style="list-style-type: none"> <li>1. For derived results, each test result used in the derived result formula should be checked. If the result is wrong, rectify the fault according to the flag of the result.</li> <li>2. View the date associated with the event in the log. An error occurred at a similar time. If an error event is found, rectify the fault based on the available information or contact technical support.</li> <li>3. Repeat detection For a derived result, repeat all the tests included in the derived result formula. If the problem persists, contact technical support personnel.</li> </ol>
CLT	<p>Clots were detected in sample tubes prior to partitioning or in reaction containers during treatment.</p>	<ol style="list-style-type: none"> <li>1. View the error events close to the event date and time in the log.</li> <li>2. Repeat detection.</li> <li>3. If the fault persists, contact technical support personnel.</li> </ol>
IND	<ul style="list-style-type: none"> <li>• For sandwich assays, the</li> </ul>	<ol style="list-style-type: none"> <li>1. View the error events close to the event date and time in the log.</li> </ol>

	<p>results are at the low dose end of the curve. The RLU value or concentration is too low to distinguish the results from a system error.</p> <ul style="list-style-type: none"> <li>• For competitive assays, the results are at the low - or high-dose end of the curve. The results cannot be distinguished from a system error because the RLU value is too high or too low.</li> </ul>	<p>If an event occurs, contact technical support personnel.</p> <p>Run quality control, and then repeat detection.</p> <p>If quality control is not within the scope, the fault should be rectified.</p> <p>If you have any doubt about the result or the problem persists, contact technical support personnel.</p>
QNS	<p>The sample container was insufficient during the treatment.</p>	<ol style="list-style-type: none"> <li>1. View error events in the event log.</li> <li>2. Repeat detection.</li> <li>3. If the fault persists, contact technical support personnel.</li> </ol>
RLU	<p>The Relative Light Units (RLU) are outside the acceptable illuminance meter measurement range.</p>	<ol style="list-style-type: none"> <li>1. In Event Log, view the error events close to the date and time of the Event.</li> <li>2. Repeat detection.</li> <li>3. If the fault persists, contact technical support personnel.</li> </ol>
SYS	<p>A device error occurred during processing.</p>	<ol style="list-style-type: none"> <li>1. In Event Log, view the error events close to the date and time of the Event.</li> </ol>

		<p>2. Repeat detection.</p> <p>3. If the fault persists, contact technical support personnel.</p>
TRI	<p>When the test is incubating, the incubating temperature exceeds the acceptable range, indicating that the temperature of the reaction table exceeds the normal range.</p>	<p>1. The incubation temperature should be regularly monitored on this interface until it enters the acceptable range.</p> <p>If the instrument has been restarted or the instrument cover has recently been opened, you will need to wait up to 10 minutes for the temperature to return to normal.</p> <p>If the system power is off for an extended period of time, you will need to wait up to an hour for the temperature to return to normal.</p> <p>2. Repeat the test after the temperature reaches the acceptable range.</p> <p>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</p>
TRIH	<p>When the test is in the process of culture, the incubation temperature exceeds the acceptable range, indicating that the incubation tray temperature is too high.</p>	<p>1. The incubation temperature should be regularly monitored on this interface until it enters the acceptable range.</p> <p>If the instrument has been restarted or the instrument cover has recently been opened, you will need to wait up to 10 minutes for the temperature to return to normal.</p>

		<p>If the system power is off for an extended period of time, you will need to wait up to an hour for the temperature to return to normal.</p> <ol style="list-style-type: none"> <li>2. Repeat the test after the temperature reaches the acceptable range.</li> <li>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</li> </ol>
<p>TRS</p>	<p>When the substrate is being distributed, the substrate temperature exceeds the acceptable range, indicating that the substrate temperature exceeds the normal range.</p>	<ol style="list-style-type: none"> <li>1. If the instrument has been restarted or the instrument cover has recently been opened, you need to wait up to 10 minutes for the temperature to return to normal. If the system power is off for an extended period of time, you will need to wait up to an hour for the temperature to return to normal.</li> <li>2. Repeat the test after the temperature reaches the acceptable range.</li> <li>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</li> </ol>
<p>TRSH</p>	<p>When the substrate is being distributed, the substrate temperature exceeds the acceptable range, indicating that the</p>	<ol style="list-style-type: none"> <li>1. If the instrument has been restarted or the instrument cover has recently been opened, you need to wait up to 10 minutes for the temperature to return to normal. If the system power is off for an extended period of time,</li> </ol>

	<p>substrate temperature is too high.</p>	<p>you will need to wait up to an hour for the temperature to return to normal.</p> <ol style="list-style-type: none"> <li>2. Repeat the test after the temperature reaches the acceptable range.</li> <li>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</li> </ol>
<p>TRR</p>	<p>It indicates that the reagent carousel temperature exceeds the normal range.</p>	<ol style="list-style-type: none"> <li>1. If the instrument has been restarted or the instrument cover has recently been opened, you need to wait up to 10 minutes for the temperature to return to normal. If the system power is off for an extended period of time, you will need to wait up to an hour for the temperature to return to normal.</li> <li>2. Repeat the test after the temperature reaches the acceptable range.</li> <li>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</li> </ol>
<p>TRRH</p>	<p>The temperature of reagent carousel is too high.</p>	<ol style="list-style-type: none"> <li>1. If the instrument has been restarted or the instrument cover has recently been opened, you need to wait up to 10 minutes for the temperature to return to normal. If the system power is off for an extended period of time, you will need to wait up to an hour for the</li> </ol>

		<p>temperature to return to normal.</p> <p>2. Repeat the test after the temperature reaches the acceptable range.</p> <p>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</p>
QSB	Abnormal test results due to insufficient substrate during substrate separation.	<p>1. Check logs for related events.</p> <p>2. Change the substrate.</p> <p>3. If the fault persists, contact technical support personnel.</p>
ERR	Test exceptions are caused by undetectable causes.	<p>1. If an exception occurs due to undetectable reasons (such as unexpected shutdown), please search for related events in the log.</p> <p>2. If the fault persists, contact technical support personnel.</p>
QWB	Lack of lotion or purified water while testing is in progress.	Please check the amount of consumable lotions remaining.
QNR	Lack of reagent.	<p>Please check the amount of reagent left after the experiment.</p> <p>If the remaining amount is normal, contact technical support personnel.</p>
TRR	It indicates that the reagent carousel temperature exceeds the normal range.	1. If the instrument has been restarted or the instrument cover has recently been opened, you need to wait up to 10 minutes for the



		<p>temperature to return to normal. If the system power is off for an extended period of time, you will need to wait up to an hour for the temperature to return to normal.</p> <ol style="list-style-type: none"> <li>2. Repeat the test after the temperature reaches the acceptable range.</li> <li>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</li> </ol>
TRRH	The temperature of reagent carousel is too high.	<ol style="list-style-type: none"> <li>1. If the instrument has been restarted or the instrument cover has recently been opened, you need to wait up to 10 minutes for the temperature to return to normal. If the system power is off for an extended period of time, you will need to wait up to an hour for the temperature to return to normal.</li> <li>2. Repeat the test after the temperature reaches the acceptable range.</li> <li>3. If the temperature does not return to normal or the problem persists, contact technical support personnel.</li> </ol>
QSB	Abnormal test results due to insufficient substrate during substrate separation.	<ol style="list-style-type: none"> <li>1. Check logs for related events.</li> <li>2. Change the substrate.</li> <li>3. If the fault persists, contact technical support personnel.</li> </ol>

ERR	Test exceptions are caused by undetectable causes.	<p>1. If an exception occurs due to undetectable reasons (such as unexpected shutdown), please search for related events in the log.</p> <p>2. If the fault persists, contact technical support personnel.</p>
QWB	Lack of lotion or purified water while testing is in progress.	Please check the amount of consumable lotions remaining.
QNR	Lack of reagent.	<p>Please check the amount of reagent left after the experiment.</p> <p>If the remaining amount is normal, contact technical support personnel.</p>
DRK	The dark value is abnormally high.	Please contact technical support personnel.

## Appendix 2- Non-serious Flags

Flag	Description	Correct operation
CEX	The calibration curve or threshold is out of date.	Repeat testing, and re-calibrate analysis.
REJ	Because the luminescence value is abnormal, it is not participate in the calibration calculation.	Check whether the instrument is abnormal during the calibration analysis, and re-calibrate.
OVD	This result is the result of testing after overdilution.	The software has automatically multiplied the dilution factor.
OLR	After dilution, the result multiplied by dilution is still less than the result of the calibrator with the highest concentration.	It is recommended that retesting without dilution.
CRH	The patient's test results exceeded the upper limit of the critical range.	This is a valid test result. No change operations are required.
CRL	The patient's test results exceeded the lower limit of the critical range.	This is a valid test result. No change operations are required.
EXS	Substrate expired.	<ol style="list-style-type: none"> <li>1. Please replace the substrate bottle.</li> <li>2. Repeat detection.</li> </ol>

GRY	For qualitative or semi-quantitative analysis, patient results or quality control results are located in the designated gray area.	This is a valid test result. No change operations are required.
LEX	The kit batch number is expired.	<ol style="list-style-type: none"> <li>1. Unload all expired kits and load a new kit.</li> <li>2. Repeat detection.</li> </ol>
ORH	The result is greater than the upper limit of the normal reference range.	This is a valid test result. No change operations are required.
ORL	The value is lower than the lower limit of the normal reference range.	This is a valid test result. No change operations are required.
OVR	<p>The calculated concentration is greater than that of the largest or largest calibrator.</p> <p>This flag is used for quantitative and semi-quantitative analysis only.</p>	<ol style="list-style-type: none"> <li>1. View the error events close to the event date and time in the log. If an event occurs, rectify the fault.</li> <li>2. Perform one of the following operations: If an event occurs and you perform troubleshooting steps, run quality control and then repeat the detection. If the quality control is within the range and the reported test results are greater than the maximum concentration of the calibrator (&gt;X), you can dilute the sample. To determine whether the analysis allows dilution, refer to</li> </ol>

		<p>the product guidance.</p> <p>If the quality control is not within the scope, follow the quality control troubleshooting instructions.</p> <p>If no event occurs, you can do one of the following:</p> <p>If the test results &gt;X, you can dilute the sample. To determine whether analysis allows dilution of the sample, refer to the product guidance. If dilution of the sample is allowed, the sample is diluted and the test is repeated.</p> <p>If dilution of the sample is allowed, no further action is required.</p> <p>3. If you have any doubt about the result or the problem persists, contact technical support. Personnel</p>
QCF	The result of the quality control product violates one or more quality control rules.	<ol style="list-style-type: none"> <li>1. Display the quality control icon and data interface to check which rule is not met.</li> <li>2. Follow the troubleshooting instructions for quality control.</li> </ol>
LQCF	The final quality control of the sample test project is out of control (If any quality control of high, medium and low concentration is out of	The item out of control for the last time. It is recommended to redo the quality control test or calibration.

	control, the flag of the sample test results of the subsequent item will be labeled LQCF.)	
QEX	The batch number of the quality control product is expired and is valid only for the quality control test.	<ol style="list-style-type: none"> <li>1. Add a new batch number of unexpired quality control products.</li> <li>2. Repeat detection.</li> </ol>
HCV	The calibration test result %CV exceeded the permitted range.	<ol style="list-style-type: none"> <li>1. Repeat detection.</li> <li>2. If the fault persists, contact technical support personnel.</li> </ol>
DRX	The result is derived from the formula.	This is a valid test result. No change operations are required.

## Appendix 3- Backtracking Authorization

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Company:				Company: Autobio Diagnostics Co., Ltd.	
Address:				Address: No.199, 15th Ave National Eco & Tech Zone, zhengzhou 450016, China	
Contact				Consignee: Customer Service Center	
Tel				Tel: [86]-371-6798-5313	
Fax		Zip		Zip	450016

Fault description:

The accessories sent back together with the instrument are:

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### NOTE:

1. Please read the precaution of the instrument packaging carefully.
2. Please fill the blanks in this annex and put in the box to be sent back together.

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Precautions for the instrument packaging are as follows:

1. Please pack the instrument with the original packing box if it still exists.
  2. Please pack the instrument with double layer packing if the original packing box does not exist.
    - a. Put the instrument in a box with foam in the bottom, and fill the side and top with foam, then seal the box to prevent damages caused by shocking during transportation.
    - b. After the first layer is finished, put it in a larger packing box and fill its four sides and top with foam.
    - c. Seal the outer packing box.
-

## Appendix 4- Disinfection Statement

Product Name:	Serial No.:
Model:	Backtracking Authorization:
Purchase Date:	No. of Warranty Certificate:

A

Does the internal or external of the product have ever been exposed to the following environment?

Please mark “yes” or “no” with X, then answer each of the questions below and give a detailed description in the B column.

	Yes	No		Yes	No
1 Pathological blood and body fluid			4 Chemical or material may endanger health		
2 Any other bio-hazardous substance			5 Radioactive material (please provide detail information below, including name, quantity and residual activity of the isotope)		
3 Substance that can decompose into dangerous substance			6 Other hazards		

B

Inform detailed information about the harmful substances in the environment that the product has been exposed to, including the name, quantity and related safety analysis table:

**NOTE:** If harmful substances have been used, disinfection treatment must be done.



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C

Your disinfectant method (table can be attached) is :

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D

Whether are the substances mentioned in part A or B likely to remain contaminated?

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**I guarantee the truth and efficiency of the information provided above.**

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Sign:

Date:

---

Name:

Title:

---

Company:

---

Address:

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Tel:

E-mail:

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